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Mental Health Parity Nonquantitative Treatment Limits (NQTL) Analysis

Insured Plans

The Mental Health Parity Addiction Equity Act (MHPAEA) requires group health plans and issuers to perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation (NQTL) applicable to mental health or substance use disorder (MH/SUD) benefits. This document explains how Aetna's various policies, procedures, and practices comply with the NQTL requirements of MHPAEA. This document is reviewed and updated at least annually.

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Nonquantitative Treatment Limitation Comparative Analysis:

EXPERIMENTAL, INVESTIGATIONAL, OR UNPROVEN (EIU)

Step 1: Description of the NQTL [45 CFR 146.1371(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of the NQTL,* ***(2)*** *an identification of all medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits to which the NQTL applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: EIU [45 CFR 146.137(c)(1)(i)]

For MH/SUD and M/S benefits, experimental, investigational, or unproven medications, devices, and any other treatment services are identified in Aetna's Clinical Policy Bulletins (CPBs). CPBs are internally developed policies that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that help support our decisions regarding specific services. CPBs are published on Aetna's public website. Aetna uses CPBs to guide individualized coverage decisions under our plans and to determine whether an intervention is medically necessary, experimental, investigational or unproven. The same medication, device, or other treatment service may be considered medically necessary for one condition but considered experimental for another condition based on the factors, evidentiary standards, and sources discussed herein. Additionally, the experimental status of a medication, device, or other treatment may change in response to new scientific research, clinical trials, or cohort studies that demonstrate the intervention no longer meets the definition of experimental, investigational, or unproven.

Aetna defines EIU as:

A drug, device, procedure, supply, treatment, test, or technology is considered by us to be experimental, investigational, or unproven if any of the following apply:

- It hasn't been shown through well-conducted clinical trials or cohort studies published in peer-reviewed, evidence-based scientific literature to be safe and effective for treating or diagnosing the condition or illness for which it's meant.
  - A well-conducted clinical trial means a randomized, controlled trial where the experimental intervention is compared to a control group receiving care according to best practice and study participants are randomly assigned to the experimental or control group.
  - A well-conducted cohort study means a prospective cohort study from more than one institution where the experimental intervention is compared to a group of

subjects receiving care according to best practice and where the comparison group is well matched to the experimental intervention group.

- There isn't FDA approval or clearance to market it for the proposed use.
- A national medical society, dental society, or regulatory agency has written that it's experimental, investigational, or unproven, or mainly for research purposes.
- It's the subject of a Phase I, Phase II, or the experimental or research arm of a Phase III clinical trial. The FDA and Department of Health and Human Services define these.
- Written procedures or consent form used by a facility [provider] says it's experimental, investigational, or unproven.

1. Plan Documents

Virgina ALIC standard certificate of coverage provides:

Certificate of Coverage - VA AL HCOC 14

Glossary definition, page 98

Experimental, investigational, or unproven

A drug, device, procedure, supply, treatment, test, or technology is considered by us to be **experimental, investigational, or unproven** if any of the following apply:

- It hasn't been shown through well-conducted clinical trials or cohort studies published in peer-reviewed, evidence-based scientific literature to be safe and effective for treating or diagnosing the condition or illness for which it's meant.
  - A well-conducted clinical trial means a randomized, controlled trial where the experimental intervention is compared to a control group receiving care according to best practice and study participants are randomly assigned to the experimental or control group.
  - A well-conducted cohort study means a prospective cohort study from more than one institution where the experimental intervention is compared to a group of subjects receiving care according to best practice and where the comparison group is well matched to the experimental intervention group.
- There isn't FDA approval or clearance to market it for the proposed use.
- A national medical society, dental society, or regulatory agency has written that it's **experimental, investigational, or unproven**, or mainly for research purposes.
- It's the subject of a Phase I, Phase II, or the experimental or research arm of a Phase III clinical trial. The FDA and Department of Health and Human Services define these.
- Written procedures or consent form used by a facility **[provider]** says it's **experimental, investigational, or unproven**.

Important note:

We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

General plan exclusions, page 51

Experimental, investigational, or unproven

Experimental, investigational, or unproven drugs, devices, treatments or procedures unless otherwise covered under clinical trials

2. Provider Contracts

Aetna's template provider agreement for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to EIU. The same template provider contract is used for both M/S and MH/SUD providers. The agreement provides "Provider agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Provider agrees to comply with Company Policies, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria; Provider Manuals; clinical policy bulletins; credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, complaint and appeals, and other policies and procedures (as modified from time to time), that are made available to Provider electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

3. Facility Contracts

In addition, Aetna's template contract for facility providers sets forth the obligations of Aetna's participating facilities with respect to EIU. The contract provides "Facility agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Facility agrees to comply with Company Policies

of which Facility knows or reasonably should have known, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria, Provider Manuals, clinical policy bulletins, credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, Institutes of Excellence™, complaint and appeals, and other policies and procedures (as modified from time to time) that are made available to Facility electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

4. Provider Manuals

These requirements are referenced in Aetna's Provider Manual, applicable to participating providers. Please see Appendix A for the Provider Manual provisions applicable to precertification.

5. Policies and Procedures

The following internal policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address EIU.

- **AETNQM-070772:** Aetna Clinical Policy Council Charter explains the function of the Aetna Clinical Policy Council, which evaluates the safety, effectiveness, and appropriateness of medical technologies (i.e., drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided) that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans.
- **AETNQM-070547:** Process for Review and Approval of Aetna Clinical Policy Bulletins (CPBs) documents Aetna's national policy and process for developing clinical policies regarding the experimental, investigational, or unproven status and medical necessity of medical technologies that may be eligible for coverage under Aetna's health plans.
- **NCS 503: Medical Review Policy and Procedure** defines the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
- **National Clinical Services (NCS) 503 Medical Review – Virginia.** This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.

Additionally, Aetna's Care Management Program Description ("**UM Program Description**") encompasses Aetna's utilization management program. The UM Program Description supports

Aetna's medical necessity review processes and details the accountability and structure of the committees responsible for reviewing, updating, and adopting the clinical criteria used in medical necessity reviews and the policies and procedures for applying clinical criteria.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137 (c)(1)(iii)]

Benefits and Classification

Attached as "VA_EIU CPT Code list.xls" is a listing of all procedure codes that are considered experimental, in accordance with the indications identified in Aetna CPBs for both M/S and MH/SUD services and conditions in the inpatient and outpatient office and outpatient all other benefit classifications. The list also indicates whether the service is always considered EIU of it is conditional. An intervention may be considered EIU for some conditions, but not others. Nine services on the code list are always considered EIU.

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **INN OP AO** ✔ **INN OP Office** ✔ **OON IP** ✔ **OON OP Office** ✔ **OON OP AO**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
2,684	235

Blanket Policy Exclusions – The below list are general exclusions from the VA COC that are always considered E/I/U.

- Full body CT scans– CPB 0603
- Hair analysis – CPB 0300
- Hypnosis and hypnotherapy – CPB 0759
- Sensory or hearing and sound integration therapy – CPB 0256

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137 (c)(2)]

In accordance with 45 CFR 146.137*(c)(2), this Step 2 is addressed in two Parts:* ***(1)*** *design, and* ***(2)*** *application of the NQTL. Each subpart includes,* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137 (c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL.

Factor	Applicable to M/S	Applicable to MH/SUD
Quality care and service to members	✓	✓
Accordance with generally accepted standards of medical practice	✓	✓
Cost management	✓	✓

- **Quality care and service to members** is a **factor** and **strategy** supporting Aetna's medical necessity processes and EIU determinations for M/S and MH/SUD benefits, to facilitate quality care and service to members. The **evidentiary standards** and **sources** upon which this factor is based are:
    - The National Committee for Quality Assurance Standards and Guidelines for the Accreditation of Health Plans and National Committee for Quality Assurance Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Utilization Management ("NCQA UM" and "NCQA MBHO UM"). The source for these evidentiary standards is NCQA, an accrediting body providing guidance on utilization review programs, including the selection and application of

medical necessity guidelines, as implemented through Aetna's UM Program Description.

- **Accordance with generally accepted standards of care**, means, pursuant to Virginia certificate of coverage, standards based on credible scientific evidence published in peer-reviewed medical literature and generally recognized by the relevant medical community. The **evidentiary standards and sources** upon which this factor is based are:
  - Peer-reviewed published medical literature, including literature indexed in the National Library of Medicine PubMed Database.
  - In general, Aetna Clinical Policy Bulletins contain the evidentiary standards (i.e., clinical treatment guidelines) that are used in the design of this NQTL to support the factor of accordance with generally accepted standards of medical practice. However, for insured plans, applicable state law may require Aetna to apply an alternative criterion.

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not EIU. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
  - Stakeholder pressure to control costs of benefits.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137 (c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL.

Factor	Applicable to M/S	Applicable to MH/SUD
Outcome data	✓	✓
FDA approval	✓	✓
National medical society or regulatory agency evaluation	✓	✓
Clinical trial	✓	✓

- **Outcome data:** the absence of evidence from credible scientific literature. The **evidentiary standards** and **sources** for this factor are:
    - Peer-reviewed published medical literature found in sources including the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database, PubMed, and Open Evidence.

- **FDA approval:** the absence of FDA approval, which is the result of a structured risk-benefit framework by the US Food & Drug Administration. The **evidentiary standards** and **sources** for this factor are:
    - Regulatory status of the medical technology, including FDA and other regulatory bodies.

- **National medical society or regulatory agency evaluation:** a national medical or dental society or regulatory agency has stated in writing that the drug, device, procedure, supply, treatment, test, or technology is experimental or investigational or suitable mainly for research purposes. The **evidentiary standards** and **sources** for this factor are:
    - Opinions and evaluations by national medical associations, consensus panels, or other evaluation bodies.

- **Clinical trials:** a drug, device, procedure, supply, treatment, test, or technology is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial. The **evidentiary standards** and **sources** for this factor are:
    - The FDA, Department of Health and Human Services, and the National Library of Medicine.

Step 3: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45CFR 146.137(c)(3)]

- **Quality care and service to members** is a factor and strategy supporting Aetna's EIU processes.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of quality care and service to members applies equally to all M/S and MH/SUD benefits, and is one factor generally underlying Aetna's EIU determinations. Aetna plans meet NCQA Health Plan and Managed Behavioral Health accreditation requirements, which include utilization review policy and process standards for conducting medical necessity review. Aetna is committed to Health Plan and Managed Behavioral Health Organization accreditation as one means of demonstrating a commitment to continuous quality improvement and meeting customer expectations.

Aetna's National Quality Oversight Committee (NQOC) annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, with consideration of recommendations from the National Quality Advisory Committee (NQAC). The NQOC is an Aetna multidisciplinary committee composed of department personnel representing both M/S and MH/SUD expertise across several functional areas. The NQOC includes representation from Aetna's behavioral health business segment for all functions: medical directors, network management, clinical health services, customer service, and quality management. The NQAC is a multidisciplinary committee, which meets quarterly, and is comprised of external practitioners, including both M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The purpose of the NQAC is to solicit feedback from Aetna's participating providers on various topics including M/S and MH/SUD medical necessity criteria. The NQOC considers the NQAC feedback and recommendations in adopting Aetna's M/S and MH/SUD medical necessity criteria. The NQOC voting member roster is included in Appendix H, and the NQAC voting member roster is included in Appendix I.

Additionally, Aetna Policy NCS 503 defines the criteria/guidelines used in medical reviews and describes the procedure for application of the clinical criteria in medical necessity reviews and decision-making.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards relied upon when designing this NQTL are the NCQA UM standards and NCQA MHBO UM standards, as implemented through Aetna's UM Program Description and Aetna policy NCS 503: Medical Review Policy

and Procedure, further explained in Step 4. These standards apply equally to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definitions as it applies to MH/SUD as compared to M/S benefits.

- **Accordance with generally accepted standards of medical practice** is a factor used in the design of this NQTL. Virginia's standard certificate of coverage defines generally accepted standards of medical practice for M/S as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and following the standards set forth in our clinical polices and applying clinical judgment." The certificate of coverage further details the relevant medical community for MH/SUD benefits as "health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment."

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor is comparably applied to all M/S and MH/SUD benefits, and is an underlying factor supporting Aetna's medical necessity programs. M/S and MH/SUD medical necessity reviews conducted by Aetna are in accordance with generally accepted standards of medical practice. Aetna's NQOC annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, with consideration of recommendations from NQAC, as described above.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** The evidentiary standards considered and relied upon when designing this NQTL are peer-reviewed published medical literature, including literature indexed in the National Library of Medicine PubMed Database. For M/S and MH/SUD benefits, the assessment of whether a drug, device, procedure, supply, treatment, test, or technology is EIU is based on the appropriate Aetna M/S and MH/SUD Clinical Policy Bulletins

(c) ***If the factor depends on specific decisions made in the administration of benefits***: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor or its applicability, as it applies in the same way to MH/SUD and M/S benefits. While the governing definitions of generally accepted standards of care are not identical between M/S and MH/SUD benefits, both are based on credible scientific evidence recognized by the relevant medical communities, and this definition is applied comparably in the application of this NQTL.

- **Cost management** is one factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management is applied equally to all M/S and MH/SUD benefits. Cost management is a general factor supporting the design of Aetna's EIU determinations.
    (b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. This standard applies equally as a general concept to all M/S and MH/SUD benefits.
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of medical necessity, cost management does not depend on specific decisions made in the administration of benefits.
    (d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of quality care and service to members, accordance with applicable accepted standards of medical practice, and cost management are applied in comparably to both M/S and MH/SUD benefits in the general design of EIU. While the governing definitions of medical necessity differ between M/S and MH/SUD benefits, both are based on generally accepted standards of care and are applied to evaluate the clinical appropriateness of requested services. They are interrelated because they collectively ensure that the plan covers only medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective medical necessity review program. Similarly, no one factor is weighted more than another in the design of EIU.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

M/S and MH/SUD drugs, devices, procedures, supplies, treatments, tests, or technologies are determined to be EIU through Aetna's CPB development and review process. The same process applies to both MH/SUD and M/S benefits. Aetna CPBs are documents developed by Aetna that describe the generally accepted standards of medical practice, credible scientific evidence, and

prevailing clinical guidelines that support Aetna's decisions regarding the experimental, investigational, or unproven status of specific M/S and MH/SUD services. Through the CPB development and review process, upon request and prior to consideration by Aetna's Clinical Policy Council (CPC), Aetna's Clinical Policy Research and Development Team evaluates and renders an opinion on the experimental, investigational, or unproven status and medical necessity of medical services or a technology that is considered for coverage under Aetna medical benefit plans. Services are reviewed pursuant to the CPB development process P&P, using the factors discussed in this analysis. The CPB development process includes annual assessment of new and emerging evidence-based information, including clinical information related to health equity. Clinical Policy Bulletins are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other relevant new information warrants more frequent review. For both M/S and MH/SUD, year over year, new CPBs are developed, and existing CPBs are subject to revisions and updates as a continual process. Approved new, revised, and updated CPBs become effective when they are published on Aetna's CPB websites.

- **Outcome data** means there is not enough outcome data available from controlled clinical trials published in the peer-reviewed literature to validate its safety and effectiveness for the illness or injury involved.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. To determine whether a medical technology is medically necessary, Aetna's CPC considers the conclusions of the scientific evidence concerning the effect of a medical technology on health outcomes, because a medical technology can significantly impact net health outcomes by improving or worsening various aspects of health, including life expectancy, quality of life, and functional abilities. The net effect is determined by considering both the benefits and harms associated with the technology.

The CPC is charged with determining whether medical technologies are considered experimental, investigational or unproven, cosmetic, or medically necessary, as those terms are defined under Aetna's medical benefit plans. The CPC is responsible for evaluating the safety, effectiveness, and appropriateness of medical technologies that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans. The CPC is comprised of one pharmacy director and medical directors representing Behavioral Health, Care Management, Commercial Appeals, Commercial Insured, Commercial Self-Insured, Commercial Individual and Family Plans, among other areas. Depending upon the topics under review at a meeting, the CPC Chair, appointed by the Aetna Chief Medical Officer, may invite others to serve as ad hoc non-voting members. Members serve for 1-year terms; members may be invited to serve consecutive years by the CMO or his/her designee. Meetings are held approximately two times a month at the call of the CMO or his/her designee. CPC

Meetings proceed according to an agenda approved by the Head of Clinical Policy Research & Development, Medical Affairs. Step 4 includes additional details about the CPC's processes. The CPC Composition is included in Appendix G.

(b) ***Explanation of the evidentiary standards considered or relied on in designing the NQTL***: The evidentiary standards relied upon when applying this factor are controlled clinical trials published in the peer-reviewed literature to validate its safety and effectiveness for the illness or injury involved, and a service is considered EIU when the safety and effectiveness cannot be validated. The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals, located in sources including the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database, PubMed, and Open Evidence. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence. A well-conducted clinical trial means a randomized, controlled trial where the experimental intervention is compared to a control group receiving care according to best practice and study participants are randomly assigned to the experimental or control group. A well-conducted cohort study means a prospective cohort study from more than one institution where the experimental intervention is compared to a group of subjects receiving care according to best practice and where the comparison group is well matched to the experimental intervention group. The evidence should demonstrate that the service can alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such alteration affects health outcomes.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **FDA approval** is the result of a structured risk-benefit framework by the US Food & Drug Administration, and the medical technology must have final approval from the appropriate governmental regulatory bodies. Without required FDA and regulatory approval, a service is considered EIU.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services, and applies to any product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. Aetna's CPC evaluates this factor as part of its determination of whether a medical technology is EIU.

(b) ***Explanation of the evidentiary standards considered or relied on in designing the NQTL***: The evidentiary standard that is relied upon when applying this factor is final approval from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. An interim approval is not sufficient, and services with interim approvals will be considered EIU. Additionally, the indications for which the technology is approved need not be the same as those which Aetna's CPC is evaluating. Please see the discussion above concerning the CPC's composition and processes.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **National medical society or regulatory agency evaluation:** A national medical or dental society or regulatory agency has stated in writing that the drug, device, procedure, supply, treatment, test, or technology is experimental or investigational or suitable mainly for research purposes.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services, and applies to any product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. Aetna's CPC evaluates this factor as part of its determination of whether a medical technology is EIU.

(b) ***Explanation of the evidentiary standards considered or relied on in designing the NQTL***: The evidentiary standard that is relied upon when applying this factor is final approval from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. An interim approval is not sufficient, and services with interim approvals will be considered EIU. Additionally, the indications for which the technology is approved need not be the same as those which Aetna's CPC is evaluating. Please see the discussion above concerning the CPC's composition and processes.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

Relationship, ordering, and weighting of multiple factors: The factors listed above apply equally to M/S and MH/SUD benefits. In determining whether a drug, device, procedure, supply, treatment, test, or technology is EIU, the CPC will consider it EIU if any one of the above-named factors are met, based on a comprehensive review of the evidentiary standards and sources described above. No factor is weighted more heavily than another, as the presence of any one factor will result in the drug, device, procedure, supply, treatment, test, or technology being considered EIU.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

*This Step 4 demonstrates that, under the terms of the plan, **as written**, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts: **(1)** design and **(2)** application. Within each such discussion, this Step 4 addresses **(a)** documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification, **(b)** in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL, **(c)** documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and **(d)** as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 2, Part 1, the factors used in the design of Aetna's EIU determinations are: 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, all of which are general design factors that apply comparably, as written, to M/S and MH/SUD services. These general design factors are the basis and rationale underlying Aetna's policies and processes related to EIU. These design factors do not distinguish between, and are applied comparably to, both M/S and MH/SUD benefits.

Quality care and service to members, as defined in Step 2, Part 1, above, is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD benefits. As provided in **Aetna's UM Program Description**, applicable to both M/S and MH/SUD benefits, Aetna seeks to provide members with access to quality care and service while coordinating needed benefits. The UM Program Description supports Aetna's medical necessity

review processes and details the accountability and structure of the committees responsible for reviewing, updating, and adopting the clinical criteria that are statements of Aetna's policy regarding the EIU status of medical technologies that may be eligible for coverage under Aetna medical plans. As explained above, each year, Aetna's NQAC reviews, and Aetna's NQOC adopts, Aetna's M/S and MH/SUD medical necessity criteria/guidelines, including Aetna CPBs. As written in the UM Program Description, the NQAC role includes "review of clinical criteria such as UM criteria, BH clinical criteria, Medical and BH Clinical Policy Bulletins (CPBs) and protocols for adoption by the NQOC." The role of the NQOC includes "adopting clinical criteria for both medical and behavioral health care and protocols with consideration of recommendations from the National Quality Advisory Committee (NQAC)." As set forth above, the NQAC is a multidisciplinary committee, which meets quarterly, and is comprised of external practitioners, including M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The purpose of the NQAC is to solicit feedback from Aetna's participating providers on various topics including M/S and MH/SUD medical necessity criteria. The NQOC, an Aetna body including representation of M/S and MH/SUD clinicians, considers the NQAC feedback and recommendations in adopting the M/S and MH/SUD medical necessity criteria. The factor of quality care and service to members, based upon evidentiary standards of NCQA UM Standards and NCQA MBHO UM Standards is further articulated through various Aetna National Clinical Services policies which apply equally to M/S and MH/SUD benefits and are discussed in Step 4, Part 2 below.

Accordance with generally accepted standards of medical practice, as defined in Step 2, Part 1, is a general design factor that does not distinguish between, and is comparably applied to, both M/S and MH/SUD benefits. Virginia's certificate of coverage defines generally accepted standards of practice as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and following the standards set forth in our clinical policies and applying clinical judgment," and the MH/SUD definition further identifies the relevant medical community. All M/S and MH/SUD medical necessity determinations are to be made in accordance with generally accepted standards of medical practice, pursuant to **NCS 503: Medical Review Policy and Procedure**. This factor is further articulated through the requirements for, and selection of, medical necessity guidelines used by Aetna clinicians conducting medical necessity reviews for M/S and MH/SUD services, as well as the process for conducting medical necessity reviews for M/S and MH/SUD services, implemented through NCS 503 and further discussed in Aetna's Precertification NQTL Treatment Limit Comparative Analysis. Aetna's CPBs are statements of Aetna's policy regarding the EIU, or cosmetic status and medical necessity of medical technologies that may be eligible for coverage under Aetna medical plans and are considered to be in accordance with generally accepted standards of medical practice. However, for insured plans, applicable state law may require Aetna to apply an alternative criterion.

Aetna's **UM Program Description** refers to each of the design factors, including cost management. The UM Program Description provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." Cost management as a design factor is further articulated in CVS Health public filings, which acknowledge that failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (*see, e.g.*, Form 10-K at page 34: "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). While these materials refer to the general design factors of promotion of cost management and clinically appropriate utilization, there is no written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of EIU with respect to M/S and MH/SUD benefits.

These design factors, 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, apply comparably to both benefit types and are not applied incomparably, or more stringently, to MH/SUD benefits in the benefit classifications noted above. Similarly, there are no deviations or variations from these three factors, as they apply to the design of EIU. As written, the processes, strategies, evidentiary standards or other factors used in designing EIU with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing EIU with respect to M/S benefits across the applicable benefit classifications.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As set forth in Step 1, for MH/SUD and M/S benefits, experimental, investigational, or unproven medications, devices, and any other treatment services are identified in Aetna's CPBs. CPBs are internally developed policies that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that help support our decisions regarding specific services. Aetna uses CPBs to guide individualized coverage decisions and to determine whether an intervention is EIU. The same drug, device, procedure, supply, treatment, test, or technology may be considered medically necessary for one condition but considered EIU for another condition based on the factors, evidentiary standards, and sources discussed in Steps 2 and 3 above. Additionally, the experimental status of a drug, device, procedure, supply, treatment, test, or technology may change in response to new scientific research,

clinical trials, or cohort studies that demonstrate the intervention no longer meets the definition of experimental, investigational, or unproven. Aetna has performed a comparative analysis and has determined that, as written, the processes, strategies, evidentiary standards and other factors used to determine that MH/SUD services are EIU are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used to determine that M/S services are EIU in the applicable benefit classifications. All written standards and processes were examined to ensure that they are based on factors and evidentiary standards that are applied comparably across MH/SUD and M/S benefits.

Comparison of EIU Standards and Policy Terms

In accordance with the member's Certificate of Coverage as set forth in Step 1, Aetna has one definition for EIU that applies to M/S and MH/SUD medications, devices, and other treatments. As to limitations and non-coverage based on EIU, both M/S and MH/SUD services that are EIU are excluded from coverage unless otherwise covered under a clinical trial as described in the Certificate of Coverage.

Comparison of Other Existing Written Documents

Specifically, Aetna applies the following internal written policies to evaluate drugs, devices, procedures, supplies, treatments, tests, and technologies and create and update CPBs describing the EIU status of those drugs, devices, procedures, supplies, treatments, tests, and technologies:

- **AETNQM070772: Aetna Clinical Policy Council Charter** - This policy explains the function of the Aetna Clinical Policy Council (CPC) which evaluates the safety, effectiveness, and appropriateness of medical technologies (i.e., drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided) that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans.
- **AETNQM-070547: Aetna Process for Review and Approval of Aetna Clinical Policy Bulletins** - defines the process the CPC uses to review new medical technologies for coverage, as well as the ongoing review and maintenance of Aetna's Clinical Policy Bulletins.

Together, these documents, along with the definition of EIU pursuant to the member's Certificate of Coverage, represent the "written" strategies and processes Aetna employs to review drugs, devices, procedures, supplies, treatments, tests, and technologies to determine which may be considered experimental or investigational in some or all circumstances. These written documents apply equally to M/S and MH/SUD services. The same CPC and other groups discussed below review all medical technologies, both M/S and MH/SUD, using the same factors, evidentiary standards and sources identified in Steps 2 and 3, and using the procedure described below.

Aetna follows a systematic, scientific process for evaluating emerging treatments that is equally applicable to MH/SUD and M/S benefits. There are no differences in the processes for evaluation of new M/S or MH/SUD treatments. For both MH/SUD and M/S benefits, EIU drugs, devices, procedures, supplies, treatments, tests, and technologies are identified in Aetna's CPBs, which are publicly available on Aetna's website. Aetna maintains one written Clinical Policy Council Charter and one written policy, AETNQM-070547: Process for Review and Approval of Aetna Clinical Policy Bulletins, which apply equally to M/S and MH/SUD services. As written in the **Clinical Policy Council Charter** and the **Process for Review and Approval of Aetna Clinical Policy Bulletins,** Aetna's CPC evaluates the safety, effectiveness, and appropriateness of medical technologies (i.e., medical and surgical procedures, devices, biological products, behavioral health interventions, and the organizational and supportive systems within which such care is provided) that may be eligible for coverage under Aetna medical plans. For both MH/SUD and M/S benefits, in making these determinations, the CPC will review and evaluate evidence in the peer-reviewed published medical literature, information from the U.S. Food and Drug Administration and other federal public health agencies, evidence-based guidelines from national medical professional organizations, and evidence-based evaluations by consensus panels and technology evaluation bodies. The CPC considers the factors, and their accompanying evidentiary standards and sources listed in Steps 2 and 3, in determining whether a drug, device, procedure, supply, treatment, test, or technology is experimental, investigational, or unproven. The presence of any one factor means the M/S or MH/SUD medication, device, or treatment is EIU. Those factors, as set forth above, are applicable to M/S and MH/SUD medications, devices, and other treatments:

- Outcome data – There is not enough outcome data available from controlled clinical trials published in the peer-reviewed literature to validate its safety and effectiveness.
- FDA approval – There is not FDA approval or clearance to market it for the proposed use.
- National medical society or regulatory agency evaluation writes that it is experimental, investigational, or unproven, or mainly for research purposes.
- Clinical trials – It is the subject of a Phase I, Phase II, or the experimental or research arm of a Phase III clinical trial.

The **Clinical Policy Council Charter** and **Process for Review and Approval of Aetna Clinical Policy Bulletins** provide, as to the process for developing CPBs, that upon request and prior to consideration by the CPC, Aetna's Clinical Policy Research and Development Team evaluates and renders an opinion on the experimental, investigational, or unproven status and medical necessity of medical services or a technology that is considered for coverage under Aetna medical benefit plans. The CPC Charter defines the CPC structure, including both M/S and MH/SUD medical directors, among other representation. The CPC is comprised of one pharmacy director and medical directors representing Behavioral Health, Care Management, Commercial Appeals, Commercial Insured, Commercial Self-Insured, Commercial Individual and Family Plans, among other areas. The CPC composition is included in Appendix G. Depending upon the topics under review at a meeting, the CPC Chair, appointed by the Aetna Chief Medical Officer,

may invite others to serve as ad hoc non-voting members. Members serve for 1-year terms; members may be invited to serve consecutive years by the CMO or his/her designee. Meetings are held approximately two times a month at the call of the CMO or his/her designee. As to how medical treatments are selected for review and the criteria for the selection, and the evidentiary standards for inclusion of medical literature in the review process, and the process for assessment of whether the medication, device, or treatment is determined to be EIU, requests typically come from Aetna's M/S and MH/SUD medical directors or other clinical staff in the context of precertification or retrospective claim review. An assessment may also be conducted at the request of other business areas of Aetna (e.g., Aetna's Special Investigations Unit, Legal Department, Aetna Senior Management), or from Aetna's National Quality Advisory Committees (NQAC) (a multidisciplinary committee comprised of external practitioners, including both M/S and MH/SUD providers who participate in Aetna's network), medical technology vendors (e.g., pharmaceutical or medical device manufacturers), or from participating Aetna health care providers. In addition, the Clinical Policy Research and Development Team may initiate an assessment at its own initiative, based on new information about a medical technology that is material to its EIU status and medical necessity. The M/S and MH/SUD interventions subject to development of a medical policy are selected based on the importance of the intervention to the plan and its members.

In developing M/S or MH/SUD CPBs, for each medical technology, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature using tools including PubMed and Open Evidence, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews relevant technology assessments indexed in the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database. In addition, the opinions of relevant experts may be obtained when necessary. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence. As set forth in the definition of experimental, investigational, or unproven, "A well-conducted clinical trial means a randomized, controlled trial where the experimental intervention is compared to a control group receiving care according to best practice and study participants are randomly assigned to the experimental or control group. A well-conducted cohort study means a prospective cohort study from more than one institution where the experimental intervention is compared to a group of subjects receiving care according to best practice and where the comparison group is well matched to the experimental intervention group."

Each CPB includes a policy statement and references to the medical literature and other sources used in developing the clinical policy. In addition, the CPB may include a "Background" section that describes the medical technology and provides the rationale for Aetna's policy. Each CPB has a coding section that provides applicable International Classification of Diseases (ICD), Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes. A detailed example of how MH/SUD treatments and M/S treatments were deemed

medically necessary versus EIU including the detailed, step-by-step explanations and documentation of how the carrier compiled, assessed, and interpreted the evidence-based sources to make its determinations is provided in Appendix L, "CPB determination examples".

Both new and revised CPB drafts undergo a comprehensive review and vote by Aetna's CPC. Once promulgated, M/S and MH/SUD CPBs are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other relevant new information warrants more frequent review. The CPB development process includes annual assessment of new and emerging evidence-based information, including clinical information related to health equity, such as that related to race, ethnicity, gender, and underserved populations. Each time a CPB is updated, a comprehensive search of the peer-reviewed, published medical literature is performed to determine if there is a change in the experimental, investigational, or unproven status or medical necessity of the medical technologies addressed. If it is determined that new evidence or other information has emerged to warrant a change in Aetna's clinical policy, a revised CPB draft is prepared. If no new evidence has emerged that would warrant a change in Aetna's position, the CPB may be updated with additional supporting background information and references. Each revised CPB is submitted to Aetna's CPC for review and approval. Approved M/S and MH/SUD CPBs are published on Aetna's websites within 60 days of the CPC's recommendations. Approved new, revised, and updated CPBs become effective when they are published on Aetna's CPB websites. A complete index of published CPBs can be found on Aetna's external CPB website.

Further, all new and revised CPBs are reviewed by Aetna's Quality Advisory Committees (also referred to as the National Quality Advisory Committee, NQAC), composed of practicing clinicians who participate in Aetna medical plans. Recommendations from Aetna's NQAC are sent to the Clinical Policy Research and Development Team for review. The Clinical Policy Research and Development Team prepares a response to each of the NQAC recommendations and may draft further revisions to the CPB as appropriate for consideration by Aetna's CPC. The QAC is co-chaired by a behavioral health medical director, and membership includes a range of participating practitioners representing both M/S and MH/SUD expertise. The full composition of the NQAC is included in Appendix I.

Additionally, Aetna's National Quality Oversight Committee (NQOC) annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, including CPBs, with consideration of recommendations from the NQAC. The NQOC is an Aetna multidisciplinary committee composed of department personnel representing both M/S and MH/SUD expertise across several functional areas. The NQOC includes representation from Aetna's behavioral health business segment for all functions: medical directors, network management, clinical health services, customer service, and quality management. The NQAC is co-chaired by a behavioral health medical director, and membership includes a range of participating practitioners representing both M/S and MH/SUD expertise. The composition of the NQOC is included in Appendix H.

The processes and procedures set forth above, which are the same for MH/SUD and M/S benefits, address how Aetna determines whether and in what circumstances a drug, device, treatment, or procedure is considered EIU, as well as how those determinations and documented in CPBs. The written policies pertaining to Aetna's CPBs discussed herein all apply equally to M/S and MH/SUD benefits. As written, there are no separate policies or procedures with respect to MH/SUD benefits. Aetna's analysis of the "as written" material used in the development of Aetna's CPBs stating the EIU status of drugs, devices, treatments or procedures, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD benefits and not more stringently applied to MH/SUD benefits.

Aetna provides members with appeal rights when an adverse benefit determination is issued. When Aetna issues a denial of services or a reduction in coverage due to an EIU determination or blanket exclusion, that determination is considered an adverse benefit determination. Members have the right to request a review of that determination through the appeal process and may initiate an appeal by contacting Aetna.

Appeal rights and procedures are described in the COC under the section titled "Appeal of an Adverse Benefit Determination." The COC outlines the appeal process, including applicable timeframes, who may request an appeal on behalf of the member, how appeals are assigned and reviewed, and the options available if the member is not satisfied with the appeal decision. Aetna does not maintain separate appeal processes for MH/SUD services and M/S services; the same appeal procedures apply to both. In addition, once the internal appeal process has been exhausted, members may have the right to request an external review, as described in the COC. The COC also explains the circumstances under which external review may be available and the procedures for requesting it. The appeal and external review rights available to members are applied consistently for MH/SUD and M/S services and are not more stringent for MH/SUD services than for M/S services.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

As noted in Step 1, Part 2, EIU applies to the following benefit classifications: 1) in-network inpatient; 2) out-of-network inpatient; 3) in-network outpatient–all other; 4) out-of-

network outpatient–all other. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying EIU to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying EIU with respect to M/S benefits.

(a) Determining the drugs, devices, treatments or procedures considered EIU

A complete index of published M/S and MH/SUD CPBs can be found on Aetna's external CPB website: Medical Clinical Policy Bulletins. In operation, the criteria for determining a medication, device, or other treatment to be EIU, and the processes and procedures for development of CPBs are the same for both M/S and MH/SUD services. The above-referenced factors, evidentiary standards and sources are applied equally, and thus comparably, to M/S and MH/SUD services. There are no separate processes applicable to MH/SUD benefits. Aetna analyzed the CPT and HCPC codes that may be subject to an EIU adverse decision and compared the medications, devices, and other medical treatments that may be considered EIU for MH/SUD conditions as documented in the CPBs. The list of codes is maintained by Aetna's Medical Policy department and is based on the implementation of the CPC determinations through the CPB development and review process.

- Of the 2,684 codes subject to an EIU exclusion under any circumstance, as described in the CPBs, 235 are EIU for MH/SUD conditions (8.76%).

(b) Denial rates and overturned appeals

Aetna analyzed the denial rates for M/S and MH/SUD EIU reviews as one measure that can evaluate whether EIU reviews are applied comparably, and not more stringently, to MH/SUD services compared to M/S services. Evaluation of this data for M/S and MH/SUD services can provide a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the EIU review process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits. The data below reflect EIU denials for in-network and out-of-network inpatient and outpatient services subject to utilization management (precertification, concurrent review, or retrospective review) for Virginia's ALIC insured book of business from July 1st 2025 through June 30th, 2026. This data is retrieved from Aetna's utilization management system and is separated by benefit classification.

Virginia Regulatory Report - E&I Combined (Prospective, Concurrent, & Retrospective)

Date Range: 07/01/2025 – 06/30/2026

Denial Rates for EIU Reviews								
ALIC	In-Network Inpatient		Out-of-Network Inpatient		In-Network Outpatient All Other		Out-of-Network Outpatient All Other	
	M/S	**MH/SUD**	**M/S**	**MH/SUD**	**M/S**	**MH/SUD**	**M/S**	**MH/SUD**

Total EIU Decisions	0	0	0	0	6	0	3	0
EIU Medical Necessity Denied Decisions	0	0	0	0	6	0	3	0
Overall Percent Denied	0%	0%	0%	0%	100%	0%	100%	0%

As demonstrated in Step 5, an in-operation review of EIU determinations for the period July 1, 2025 through June 30, 2026 reflects no EIU denials for MH/SUD services in any of the benefit classifications reviewed. For outpatient all other services, all EIU determinations resulted in denials for M/S services, while no denials were observed for MH/SUD services. These results reflect that, in operation, EIU review is applied at least comparably, and not more stringently, to MH/SUD services than to M/S services.

Furthermore, Aetna analyzed the rates of overturned appeals resulting from prior authorizations, concurrent reviews, and retrospective reviews regarding EIU determinations for MH/SUD benefits as compared to M/S benefits.

Appeal Overturn Rates for EIU Reviews 07/01/25-06/30-26						
ALIC	**Precertification**		**Concurrent Review**		**Retrospective Review**	
	M/S	**MH/SUD**	**M/S**	**MH/SUD**	**M/S**	**MH/SUD**
Total Appeals	2	0	0	0	0	0
Overturned Appeals	0	0	0	0	0	0
Overall Percent Overturned	0	0	0	0	0	0

As further demonstrated in Step 5, an in-operation review of EIU appeal determinations reflects very limited appeal activity during the review period. For M/S services, two appeals were submitted in connection with concurrent review determinations, and neither appeal resulted in an overturn. Accordingly, the overturn rate was 0% for all categories reviewed. Overall, the appeal data does not indicate that EIU determinations for MH/SUD services are overturned less frequently

than those for M/S services and reflects that the appeals process is applied at least comparably, and not more stringently, to MH/SUD services than to M/S services.

Summary

These measures were used to assess comparability and stringency in operation. Taken together, the data and reviews demonstrate that EIU adverse determinations are applied comparably, and not more stringently, to MH/SUD benefits than to M/S benefits. A smaller percentage of codes are designated as EIU for MH/SUD conditions than for M/S conditions. Consistent with the data reviewed, there were no adverse EIU determinations for MH/SUD services during the reporting period, while EIU denials for M/S services were limited to outpatient all other services. In addition, no appeals were submitted for MH/SUD EIU determinations, and the two appeals submitted for M/S concurrent review determinations resulted in the original determinations being upheld. The review of EIU denial rates, appeal outcomes, and adverse determination activity does not indicate that MH/SUD services are subject to more restrictive application of the EIU exclusion than comparable M/S services.

Accordingly, the data supports the conclusion that, in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying the EIU exclusion to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the EIU exclusion to M/S benefits in the applicable benefit classifications.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of §146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the*

comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

Aetna has performed a comparative analysis and has determined that, as written and in operation, the processes, strategies, evidentiary standards and other factors used to determine that MH/SUD drugs, devices, procedures, supplies, treatments, tests, or technologies are EIU are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used to determine that M/S drugs, devices, procedures, supplies, treatments, tests, or technologies are EIU in the applicable benefit classifications.

As demonstrated in Step 1, EIU is uniformly defined across MH/SUD and M/S services, the applicability to which is set forth in the CPBs referenced and defined in Step 1. Step 2 identified the factors used to determine MH/SUD and M/S services that are EIU. Step 3 explained the evidentiary standards and sources for those factors. As noted in Steps 2 and 3, the same factors, evidentiary standards, and sources are used with respect to MH/SUD and M/S services. There are no differences in how the factors are designed or applied to M/S and MH/SUD services.

Aetna applies the same factors, evidentiary standards, and sources, and the same written policies and procedures, the **Clinical Policy Council Charter** and the **Process for Review and Approval of Aetna Clinical Policy Bulletins,** to determine whether a drug, device, procedure, supply, treatment, test, or technology is EIU for both M/S and MH/SUD benefits. There are no separate policies or procedures that apply to MH/SUD benefits. As set forth above in Step 4, the CPC considers the factors, and their accompanying evidentiary standards and sources listed in Steps 2 and 3 in determining whether a M/S or MH/SUD medication, device or other treatment is considered EIU. There is one process, applicable to both M/S and MH/SUD benefits through which Aetna CPBs are developed, which includes the same groups, including the CPC, the NQAC, and ultimately Aetna's NQOC, responsible for reviewing and approving or adopting the CPBs. As set forth in Step 4 above, these groups include representation of professionals with both M/S and MH/SUD expertise. Based upon review of these materials, there are no arbitrary or unfairly discriminatory differences in the written standards for applying the underlying processes and strategies for determining drugs, devices, procedures, supplies, treatments, tests, or technologies to be EIU with respect to M/S benefits versus MH/SUD. Simply stated, there are no written differences in these written standards that result in any MH/SUD services being treated more stringently than, or incomparably to, M/S services. As written, the processes, strategies, evidentiary standards or other factors used in designing and applying EIU to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying EIU with respect to M/S benefits in the applicable benefit classifications.

As demonstrated in Step 5, Aetna reviewed data to assess the comparability and stringency of how EIU determinations are made, in operation. A smaller percentage of codes are considered

EIU for MH/SUD conditions compared to M/S conditions. The figures above demonstrate that in operation, of the service codes subject to an EIU exclusion under any circumstance, only 8% are EIU for MH/SUD conditions. In operation, this data demonstrates that Aetna determines drugs, devices, procedures, supplies, treatments, tests, or technologies to be EIU for MH/SUD at a significantly lower percentage than compared to M/S. Aetna also compiled and reviewed the data demonstrating denial rates and rates of overturned appeals resulting from prior authorizations, concurrent reviews, and retrospective reviews regarding EIU determinations for M/S and MH/SUD services. The data shows no adverse decisions based on EIU exclusions for any MH/SUD benefits during the reporting period, compared to their being some adverse determinations for M/S benefits. Step 5 demonstrated that, in operation, Aetna makes EIU determinations for MH/SUD services in a manner that is comparable to, and not more stringent than, M/S services.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply EIU to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying EIU with respect to M/S benefits across the applicable benefit classifications. The factors, evidentiary standards and sources used to determine which medications, devices and other treatments are EIU are designed and applied in a comparable, and not more stringent manner, for MH/SUD benefits. Taken together with the data discussed herein, the EIU NQTL is designed and applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Executive Director, National Quality Management, Medical Doctor in General Practice • Behavioral Health Senior Medical Director, Quality, Medical Doctor board certified in Psychiatry

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Nonquantitative Treatment Limitation Comparative Analysis:

MEDICAL NECESSITY

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of medical necessity, and* ***(2)*** *an identification of all mental health or substance use disorder (MH/SUD) and medical or surgical (M/S) benefits to which medical necessity applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Medical Necessity [45 CFR 146.137(c)(1)(i)]

Based upon Virginia's standard certificate of coverage, "medical necessity" and/or "medically necessary" refer to health care services or supplies that prevent, evaluate, diagnose or treat an illness, injury, disease or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with generally accepted standards of medical practice
- Clinically appropriate, in terms of type, frequency, extent, site, place of service, duration, and considered effective for the illness, injury or disease
- Not primarily for the member's convenience, the convenience of the member's physician, or other health care provider
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the illness, injury, or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, and
- Following the standards set forth in our clinical policies and applying clinical judgment

These elements are incorporated into the following criteria/guidelines used by Aetna's clinicians in making medical necessity determinations:

- Aetna Clinical Policy Bulletins
- MCG Health Care Guidelines
- National Comprehensive Cancer Network (NCCN) guidelines

- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions*
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS)
- Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII)
- Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide

The Virginia standard certificate of coverage specifies a separate definition for mental health or substance use disorder services which is documented below in the "Plan Document" section.

1. Plan Documents

The member's certificate of coverage defines medical necessity. Virginia ALIC standard certificate of coverage provides:

Certificate of Coverage – VA AL HCOC 14

Medical necessity[, referral, and, precertification] requirements

Medically necessary, medical necessity

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

Glossary Definition

Medically necessary, medical necessity (mental health or substance use disorder)

A service or product addressing the specific needs of a patient for the purpose of screening, preventing, diagnosing, managing, or treating such disorder, including:

- Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care
- Clinically appropriate in terms of type, frequency, extent, site, and duration
- Not defined primarily for the economic benefit of an insurer or purchaser or for the convenience of the patient, treating physician, or other health care provider.

Generally accepted standards of mental health or substance use disorder care means evidence-based independent standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment. Sources reflecting "generally accepted standards of mental health or substance use disorder care" include:

- Peer-reviewed scientific studies and medical literature
- Consensus guidelines and recommendations of nonprofit health care provider professional associations and specialty societies
- Nationally recognized clinical practice guidelines, including:
  - Patient placement criteria
  - Service intensity assessment instruments
  - Clinical practice guidelines
  - Guidelines and recommendations of federal government agencies
  - Drug labeling approved by the U.S. Food and Drug Administration

Important note:

We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Medically necessary, medical necessity (other than mental health or substance use disorder)

Health care services or supplies that prevent, evaluate, diagnose or treat an illness, injury, disease or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with "generally accepted standards of medical practice"
- Clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease
- Not primarily for your convenience, the convenience of your **[physician]**, or other health care **[provider]**
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your illness, injury or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and
- Following the standards set forth in our clinical policies and applying clinical judgment

Important note:

We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

2. Provider Contracts

Aetna's template provider agreement for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to medical necessity. The same template provider contract is used for both M/S and MH/SUD providers. The agreement provides "Provider agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Provider agrees to comply with Company Policies, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria; Provider Manuals; clinical policy bulletins; credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, complaint and appeals, and other policies and procedures (as modified from time to time), that are made available to Provider electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

3. Facility Contracts

In addition, Aetna's template provider contract for facility providers sets forth the obligations of Aetna's participating facilities, relating to medical necessity. The same template is used for M/S and MH/SUD facilities. The contract provides "Facility agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Facility agrees to comply with Company Policies of which Facility knows or reasonably should have known, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria, Provider Manuals, clinical policy bulletins,

credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, Institutes of Excellence™, complaint and appeals, and other policies and procedures (as modified from time to time) that are made available to Facility electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

4. Provider Manual

Medical necessity requirements are referenced in Aetna's Provider Manual, applicable to participating providers. Please see Appendix A for Provider Manual provisions applicable to medical necessity.

5. Policies and Procedures

The following internal Aetna policies, which apply to M/S and MH/SUD benefits, address medical necessity:

- **AETNQM-070772: Aetna Clinical Policy Council Charter** explains the function of the Aetna Clinical Policy Council, which evaluates the safety, effectiveness, and appropriateness of medical technologies (i.e., drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided) that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans.
- **AETNQM-070547: Process for Review and Approval of Aetna Clinical Policy Bulletins (CPBs)** documents Aetna's national policy and process for developing clinical policies regarding the experimental, investigational, or unproven status and medical necessity of medical technologies that may be eligible for coverage under Aetna's health plans.
- **NCS 503: Medical Review Policy and Procedure** defines the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
- **NCS 503: Medical Review Policy and Procedure Virginia Amendment -** This Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 503 Medical Review Policy and Procedure. This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
- **NCS 505: Denial of Coverage Policy and Notification** defines and outlines the handling of denial of coverage determinations.
- **NCS 505: Denial of Coverage Policy and Notification Virginia Amendment** – This Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 505 Denial of Coverage Policy and Notification. This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements.

- **NCS 506: Peer-to-Peer Review Policy** describes the process for treating practitioners/clinicians/physicians to discuss a clinical denial with a peer reviewer or behavioral health consultant/psychiatrist/psychologist.
- **NCS 506: Peer-to-Peer Review Policy Virginia Amendment -** This Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 506 Peer-to-Peer Review Policy. This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.
- **NCS 510: Internal Quality Review Policy** describes the internal quality review process to assess the performance of individuals who support the health plan's medical management programs.

Additionally, Aetna's Care Management Program Description (**"UM Program Description"**) encompasses Aetna's utilization management program. The UM Program Description supports Aetna's medical necessity review processes and details the accountability and structure of the committees responsible for reviewing, updating, and adopting the clinical criteria used in medical necessity reviews and the policies and procedures for applying clinical criteria.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Benefits and Classification

Medical necessity applies to all M/S and MH/SUD benefits in all benefit classifications, as all M/S and MH/SUD services must be medically necessary to be eligible for coverage: **in-network** and **out-of-network inpatient; in-network** and **out-of-network outpatient, both office** and **all other** subclassifications, and **emergency**.

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **OON IP** ✔ **INN OV** ✔ **OON OV** ✔ **INN OP AO** ✔ **OON OP AO** ✔ **Emergency**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
All M/S services must be medically necessary.	All MH/SUD services must be medically necessary.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of medical necessity. Each subpart includes:* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to medical necessity, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL:

Factor	Applicable to M/S	Applicable to MH/SUD
Quality care and service to members	✓	✓
Accordance with generally accepted standards of medical practice	✓	✓
Cost management	✓	✓

- **Quality care and service to members** is a **factor** and **strategy** supporting Aetna's medical necessity processes for M/S and MH/SUD benefits, to facilitate quality care and service to members. The **evidentiary standards** and **sources** upon which this factor is based are:
    - The National Committee for Quality Assurance Standards and Guidelines for the Accreditation of Health Plans and National Committee for Quality Assurance Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Utilization Management ("NCQA UM" and "NCQA MBHO UM"). The source for these evidentiary standards is NCQA, an accrediting body providing guidance on utilization review programs, including the selection and application of medical necessity guidelines, as implemented through Aetna's UM Program Description.

- **Accordance with generally accepted standards of care**, means, pursuant to Virginia certificate of coverage, standards based on credible scientific evidence published in peer-reviewed medical literature and generally recognized by the relevant medical community. The **evidentiary standards and sources** upon which this factor is based are:
    - Peer-reviewed published medical literature, including literature indexed in the National Library of Medicine PubMed Database.
    - In general, Aetna Clinical Policy Bulletins contain the evidentiary standards (i.e., clinical treatment guidelines) that are used in the design of this NQTL to support the factor of accordance with generally accepted standards of medical practice. However, for insured plans, applicable state law may require Aetna to apply an alternative criterion.

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of medical necessity for: (a) developing Aetna CPBs used in the medical necessity determination process; (b) selection of nationally recognized third-party clinical guidelines used in the medical necessity determination process; and (c) the process for making medical necessity determinations:

(a) Factors for developing Aetna Clinical Policy Bulletins (CPBs) used in the medical necessity determination process

Aetna CPBs are documents developed by Aetna that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's medical necessity decisions regarding specific M/S and MH/SUD services. These CPBs, in conjunction with the terms of the member's benefit plans, are used to help guide individualized coverage determinations under Aetna's medical plans and to determine whether an intervention is medically necessary, experimental, investigational, or unproven. During the CPB development process, Aetna's Clinical Policy Council ("CPC") considers the following factors for determining whether a medical technology is medically necessary, for M/S and MH/SUD services:

Factor	Applicable to M/S	Applicable to MH/SUD
The medical technology must have final approval from the appropriate governmental regulatory bodies	✓	✓
The scientific evidence must permit conclusions concerning the effect of the medical technology on health outcomes	✓	✓
The medical technology must improve the net health outcome	✓	✓
The medical technology must be as beneficial as any established alternatives	✓	✓
The improvement must be attainable outside the investigational settings	✓	✓

- **The medical technology must have final approval from the appropriate governmental regulatory bodies**. The **evidentiary standards and sources** upon which this factor is based are:
    - Final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology.

- **The scientific evidence must permit conclusions concerning the effect of the medical technology on health outcomes**. The **evidentiary standards and sources** upon which this factor is based are:
    - Evidence consisting of well-designed and well-conducted investigations published in peer-reviewed journals.
    - Evidence demonstrating that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes.
    - Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

- **The medical technology must improve the net health outcome**. The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes. The **evidentiary standards and sources** upon which this factor is based are:
    - Evidence consisting of well-designed and well-conducted investigations published in peer-reviewed journals.
    - Evidence demonstrating that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes.
    - Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

- **The medical technology must be as beneficial as any established alternatives**. The **evidentiary standards and sources** upon which this factor is based are:
    - The technology should improve the net health outcome as much as, or more than, established alternatives.
    - The technology must be no more costly (taking into account all health expenses incurred in connection with the technology) than any equally effective established alternative.
    - Evidence consisting of well-designed and well-conducted investigations published in peer-reviewed journals.
    - Evidence demonstrating that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes.

- Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

- **The improvement must be attainable outside the investigational settings**. The **evidentiary standards and sources** upon which this factor is based are:
  - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy the above-listed factors.

(b) Factors for selection of nationally recognized third-party clinical guidelines used in the medical necessity determination process

Factor	Applicable to M/S	Applicable to MH/SUD
The clinical criteria must be objective and based on medical evidence	✓	✓
Involvement of appropriate practitioners in developing, adopting, and reviewing criteria	✓	✓
Applicable state law	✓	✓

- **The clinical criteria must be objective and based on medical evidence.** The **evidentiary standards and sources** upon which this factor is based are:
  - NCQA Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, as implemented through Aetna's UM Program Description, Aetna's National Clinical Services (NCS) policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment.
  - Well-conducted clinical trials or cohort studies published in peer-reviewed, evidence-based scientific literature to be safe and effective for treating or diagnosing the condition or illness for which it is meant.

- **Involvement of appropriate practitioners in developing, adopting, and reviewing criteria.** The **evidentiary standards and sources** upon which this factor is based are:
  - NCQA Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, as implemented through Aetna's UM Program Description.

- **Applicable state law.** Some states require specific medical necessity guidelines to be used in medical necessity reviews. The **evidentiary standards and sources** for this factor are:
  - Clinical criteria or guidelines required by state law, as applicable.

(c) Factors for the process of making medical necessity determinations

In the process of making medical necessity determinations, Aetna clinical staff apply clinical guidelines to a coverage request after verifying that the member is eligible for benefits, the services requested are not excluded from coverage, and benefits are available (i.e., limited benefits are not exhausted). The factors considered or relied upon in the process of making medical necessity determinations are:

Factor	Applicable to M/S	Applicable to MH/SUD
Review of all available, pertinent, clinical information by appropriate clinical professionals	✓	✓
Individual needs of the member	✓	✓
Characteristics of the local health care delivery system	✓	✓

- **Review of all available, pertinent, clinical information by appropriate clinical professionals.** Appropriate clinical professionals review all pertinent clinical information submitted by members or providers as part of the coverage determination process. Clinical staff make coverage determinations using this member-specific clinical information to determine whether the coverage request meets the applicable criteria/guidelines. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA Standards and Guidelines, specifically, and UM 4 and MBHO UM 4, and UM 6 and MBHO UM 6, as implemented through Aetna's National Clinical Services (NCS) Policy 503: Medical Review Policy and Procedure and NCS Policy 503: Medical Review Policy and Procedure Virginia Amendment.

- **Individual needs of the member** means that Aetna clinical staff consider the individual needs of the member when applying clinical criteria or guidelines during the medical necessity determination process. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA Standards and Guidelines, specifically, UM2 and MBHO UM2: Clinical Criteria for UM Decisions, as implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment.

- **Characteristics of the local health care delivery system** means that Aetna clinical staff additionally consider the available services in the local health care delivery system and their ability to meet the member's specific health care needs during the medical necessity determination

process. The health care delivery system encompasses all the people, institutions, and services that contribute to care coordination, patient flows, diagnosis, disease management, and health maintenance programs. The **evidentiary standards and sources** upon which this factor is based are:

- NCQA Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, as implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment.

Step 3: Description of How Factors are Used in the Design or Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Quality care and service to members** is a factor and strategy supporting Aetna's medical necessity processes.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of quality care and service to members applies equally to all M/S and MH/SUD benefits, and is one factor generally underlying Aetna's medical necessity programs. Aetna plans meet NCQA Health Plan and Managed Behavioral Health accreditation requirements, which include utilization review policy and process standards for conducting medical necessity review. Aetna is committed to Health Plan and Managed Behavioral Health Organization accreditation as one means of demonstrating a commitment to continuous quality improvement and meeting customer expectations.

Aetna's National Quality Oversight Committee (NQOC) annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, with consideration of recommendations from the National Quality Advisory Committee (NQAC). The NQOC is an Aetna multidisciplinary committee composed of department personnel representing both M/S and MH/SUD expertise across several functional areas. The NQOC includes representation from Aetna's behavioral health business segment for all functions: medical directors, network management, clinical health services, customer service, and quality management. The NQAC is a multidisciplinary committee, which meets quarterly, and is comprised of external practitioners, including both M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The purpose of the NQAC is to solicit feedback from Aetna's participating providers on various topics including M/S and MH/SUD medical necessity criteria. The NQOC considers the NQAC feedback and recommendations in adopting Aetna's M/S and MH/SUD medical necessity criteria. The NQOC voting member roster is included in Appendix H, and the NQAC voting member roster is included in Appendix I.

Additionally, Aetna Policy NCS 503: Medical Review Policy and Review Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment defines the criteria/guidelines used in medical reviews and describes the procedure for application of the clinical criteria in medical necessity reviews and decision-making.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards relied upon when designing this NQTL are the NCQA UM standards and NCQA MHBO UM standards, as implemented through Aetna's UM Program Description, Aetna policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment further explained in Step 4. These standards apply equally to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definitions as it applies to MH/SUD as compared to M/S benefits.

- **Accordance with generally accepted standards of medical practice** is a factor used in the design of this NQTL. Aetna's standard certificate of coverage defines generally accepted standards of medical practice as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and following the standards set forth in our clinical polices and applying clinical judgment." The certificate of coverage further details the relevant medical community for MH/SUD benefits as

"health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment."

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor is comparably applied the to all M/S and MH/SUD benefits, and is an underlying factor supporting Aetna's medical necessity programs. M/S and MH/SUD medical necessity reviews conducted by Aetna are in accordance with generally accepted standards of medical practice. Aetna's NQOC annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, with consideration of recommendations from NQAC, as described above.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** The evidentiary standards considered and relied upon when designing this NQTL are peer-reviewed published medical literature, including literature indexed in the National Library of Medicine PubMed Database and those generally accepted standards of care identified above in Step 2, Part 1 (e.g., MCG, LOCUS, CALOCUS). For M/S benefits, the assessment of whether care is clinically appropriate in the context of medical necessity relies on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. For MH/SUD benefits, clinically appropriate utilization is based on the American Society of Addiction Medicine (ASAM) criteria: *Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), Aetna's Applied Behavioral Analysis Medical Necessity Guide, and the appropriate Aetna MH/SUD Clinical Policy Bulletins

(c) ***If the factor depends on specific decisions made in the administration of benefits***: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor or its applicability, as it applies in the same way to MH/SUD and M/S benefits. While the governing definitions of generally accepted standards of care are not identical between M/S and MH/SUD benefits, both are based on credible scientific evidence recognized by the relevant medical communities, and this definition is applied comparably in the application of this NQTL.

- **Cost management** is one factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management applies equally to all M/S and MH/SUD benefits. Cost management is a general factor supporting the design of Aetna's medical necessity programs.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of medical necessity, cost management does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of quality care and service to members, accordance with generally accepted standards of medical practice, and cost management apply equally and agnostically to both M/S and MH/SUD benefits in the general design of medical necessity. While the governing definitions of medical necessity differ between M/S and MH/SUD benefits, both are based on generally accepted standards of care and are applied to evaluate the clinical appropriateness of requested services. They are interrelated because they collectively ensure that the plan covers only medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective medical necessity review program. Similarly, no one factor is weighted more than another in the design of medical necessity.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

(a) Factors for developing Aetna Clinical Policy Bulletins used in the medical necessity determination process

Aetna's CPBs are statements of Aetna's policy regarding the experimental, investigational, unproven, or cosmetic status and medical necessity of medical technologies that may be eligible for coverage under Aetna medical plans. Aetna's CPC evaluates the safety, effectiveness, and appropriateness of medical technologies (i.e., drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided) that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans. M/S and MH/SUD medical technologies must meet all of the five bulleted criteria

below to be considered medically necessary and established by Aetna's CPC. Additionally, all new and revised CPBs are annually adopted by Aetna's NQOC, with consideration of recommendations from the NQAC, as described above.

- **The medical technology must have final approval from the appropriate governmental regulatory bodies.**
  - (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services, and applies to any product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. Aetna's CPC evaluates this factor as part of its determination of whether a medical technology is medically necessary. The CPC is charged with determining whether medical technologies are considered experimental, investigational or unproven, cosmetic, or medically necessary, as those terms are defined under Aetna's medical benefit plans. The CPC is responsible for evaluating the safety, effectiveness, and appropriateness of medical technologies that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans. The CPC is comprised of one pharmacy director and medical directors representing Behavioral Health, Care Management, Commercial Appeals, Commercial Insured, Commercial Self-Insured, Commercial Individual and Family Plans, among other areas. Depending upon the topics under review at a meeting, the CPC Chair, appointed by the Aetna Chief Medical Officer, may invite others to serve as ad hoc non-voting members. Members serve for 1-year terms; members may be invited to serve consecutive years by the CMO or his/her designee. Meetings are held approximately two times a month at the call of the CMO or his/her designee. CPC Meetings proceed according to an agenda approved by the Head of Clinical Policy Research & Development, Medical Affairs. Step 4 includes additional details about the CPC's processes. The CPC Composition is included in Appendix G.
  - (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that is relied upon when applying this factor is final approval from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. An interim approval is not sufficient. Additionally, the indications for which the technology is approved need not be the same as those which Aetna's CPC is evaluating.
  - (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
  - (d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **The scientific evidence must permit conclusions concerning the effect of the medical technology on health outcomes.**

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD services. To determine whether a medical technology is medically necessary, Aetna's CPC considers the conclusions of the scientific evidence concerning the effect of a medical technology on health outcomes, because a medical technology can significantly impact net health outcomes by improving or worsening various aspects of health, including life expectancy, quality of life, and functional abilities. The net effect is determined by considering both the benefits and harms associated with the technology. Please see the discussion above concerning the CPC's composition and processes.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are:

- Evidence consisting of well-designed and well-conducted investigations published in peer-reviewed journals;
- Evidence demonstrating that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes, and;
- Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

This evaluation is based on evidence in the peer-reviewed published medical literature, technology assessments and structured evidence reviews, evidence-based consensus statements, expert opinions of healthcare providers, and evidence-based guidelines from nationally recognized professional healthcare organizations and government public health agencies. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence. For each medical technology evaluated, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews relevant technology assessments indexed in the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database. In addition, the opinions of relevant experts may be obtained when necessary.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **The medical technology must improve the net health outcomes.**
  (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD technologies. To determine whether a medical technology is medically necessary, Aetna's CPC considers whether the medical technology improves net health outcomes and ensures a positive impact on patient health. Please see the discussion above concerning the CPC's composition and processes.
  (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are:
    - Evidence consisting of well-designed and well-conducted investigations published in peer-reviewed journals;
    - Evidence demonstrating that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes, and;
    - Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

    As above, this evaluation is based on evidence in the peer-reviewed published medical literature, technology assessments and structured evidence reviews, evidence-based consensus statements, expert opinions of healthcare providers, and evidence-based guidelines from nationally recognized professional healthcare organizations and government public health agencies. For each medical technology evaluated, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews relevant technology assessments indexed in the National Library of Medicine's HSTAT Database. In addition, the opinions of relevant experts may be obtained when necessary.
  (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
  (d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **The medical technology must be as beneficial as any established alternatives.**
  (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD technologies. To determine whether a medical technology is medically necessary, Aetna's CPC evaluates the medical technology to ensure it is at least as beneficial as, or better than, existing treatments. Please see the discussion above concerning the CPC's composition and processes.
  (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are:
    - The technology should improve the net health outcome as much as, or more than, established alternatives.
    - The technology must be no more costly (taking into account all health expenses incurred in connection with the technology) than any equally effective established alternative.
    - Evidence consisting of well-designed and well-conducted investigations published in peer-reviewed journals.
    - Evidence demonstrating that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts, that such measurement or alteration affects health outcomes.
    - Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

  As above, this evaluation is based on evidence in the peer-reviewed published medical literature, technology assessments and structured evidence reviews, evidence-based consensus statements, expert opinions of healthcare providers, and evidence-based guidelines from nationally recognized professional healthcare organizations and government public health agencies. For each medical technology evaluated, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews relevant technology assessments indexed in the National Library of Medicine's HSTAT Database. In addition, the opinions of relevant experts may be obtained when necessary.
  (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
  (d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **The improvement from the medical technology must be attainable outside the investigational settings.**

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD technologies. To determine whether a medical technology is medically necessary, Aetna's CPC considers whether improvements from the technology during controlled research studies are expected to be replicated when used under normal clinical conditions. Please see the discussion above concerning the CPC's composition and processes.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The technology should be reasonably expected to satisfy the above-listed factors, when used under the usual conditions of medical practice. As with the other factors, this evaluation is based on evidence in the peer-reviewed published medical literature, technology assessments and structured evidence reviews, evidence-based consensus statements, expert opinions of healthcare providers, and evidence-based guidelines from nationally recognized professional healthcare organizations and government public health agencies. For each medical technology evaluated, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews relevant technology assessments indexed in the National Library of Medicine's HSTAT Database. In addition, the opinions of relevant experts may be obtained when necessary.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

Relationship, ordering, and weighting of multiple factors: In determining whether a medical technology is medically necessary and established, the CPC will consider whether all five factors are met, based on a comprehensive review of the evidentiary standards and sources described above. No factor is weighted more heavily than another, as all five factors must be demonstrated in order for a technology to be deemed medically necessary.

(b) Factors for selection of nationally recognized third-party clinical guidelines for the medical necessity determination process

- **The clinical criteria must be objective and based on medical evidence,** which means the criteria is backed by well-conducted clinical trials or cohort studies published in peer-reviewed, evidence-based scientific literature**.**

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. For selection of nationally recognized third-party clinical guidelines to be used by Aetna clinicians when making medical necessity determinations, Aetna considers generally accepted standards of medical practice, annually reviews the medical necessity criteria and procedures for applying them and updates the criteria when appropriate. The NQOC, as described above, and including representation of both M/S and MH/SUD clinicians and professionals, annually reviews and adopts the M/S and MH/SUD medical necessity criteria, with consideration of recommendations from the NQAC non-staff network practitioners, as described above.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA UM and NCQA MBHO UM 2, Clinical Criteria for UM Decisions, which require Aetna to: 1) use written criteria based on sound clinical evidence to make utilization determinations; 2) involve appropriate practitioners in developing, adopting, and reviewing criteria; and 3) annually review the criteria and procedures for applying them and updating the criteria when appropriate. These NCQA guidelines are implemented through Aetna's UM Program Description, Aetna policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment. For sound clinical evidence, the evidentiary standards relied upon are well-conducted clinical trials or cohort studies published in peer-reviewed, evidence-based scientific literature.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies to MH/SUD as compared to M/S services.

- **Involvement of appropriate practitioners in developing, adopting, and reviewing criteria**

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. The NQOC, as described above, and including representation of both M/S and MH/SUD clinicians and professionals, annually reviews and adopts the M/S and MH/SUD medical necessity guidelines to be used by Aetna clinicians when making medical necessity determinations, with

consideration of recommendations from the NQAC non-staff network practitioners, as described above.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA UM and NCQA MBHO UM 2, Clinical Criteria for UM Decisions, as implemented through Aetna's UM Program Description, which require Aetna to involve appropriate practitioners in developing, adopting, and reviewing clinical criteria and annually review the criteria and procedures for applying them and updating the criteria when appropriate. The practitioners involved in adopting the medical necessity guidelines are the M/S and MH/SUD clinicians serving on Aetna's NQOC and NQAC, as described above.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **Applicable state law refers to** regulatory requirements related to state-specific medical necessity criteria.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Aetna complies with applicable state requirements to use specific guidelines or criteria in making medical necessity determinations.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon are applicable state requirements to use specific criteria for medical necessity determinations. When state laws/regulations vary from the core requirements of Aetna's NCS policies, they are documented in a state amendment. Aetna's NQOC approves the state amendments to the NCS policies, which reflect any state requirements for specific criteria to be used by clinicians when making medical necessity determinations.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Application of this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

Relationship, ordering, and weighting of multiple factors: The factor of state law is weighted more heavily than the other factors, due to the primary importance of ensuring compliance with

applicable law. In states where Aetna selects the third-party clinical guidelines used in making medical necessity determinations, the factors of 1) objective clinical guidelines based on medical evidence and 2) the involvement of appropriate practitioners in adopting and annually reviewing guidelines and updating those guidelines when appropriate are weighted equally. These two factors are interrelated and operate together to ensure that Aetna selects appropriate nationally recognized third-party clinical guidelines to be used by Aetna clinicians during the medical necessity determination process.

(c) Factors for the process of making medical necessity determinations

In the process of making M/S and MH/SUD medical necessity determinations, Aetna clinical staff apply clinical guidelines/criteria to a coverage request after verifying that the member is eligible for benefits, the services requested are not excluded from coverage, and benefits are available (i.e., limited benefits are not exhausted). The following explains how the factors are used in the process of making medical necessity determinations:

- **Review of all available, pertinent, clinical information submitted as part of the coverage determination process by appropriate clinical professionals.** Clinical staff make coverage determinations using member-specific clinical information to determine whether the coverage request meets the applicable criteria/guidelines.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Clinical staff draw upon their training and expertise to make coverage determinations using all available, pertinent, member-specific clinical information to determine whether the coverage request meets the applicable criteria/guidelines.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon in the application of this factor are NCQA UM Standards and Guidelines, specifically, UM 4 and MBHO 4: Appropriate Professionals and UM 6 and MBHO UM 6: Clinical Information, as implemented through Aetna's Policy NCS 503: Medical Review Policy and Procedure, NCS 503: Medical Review Policy and Procedure Virginia Amendment, NCS 505: Denial of Coverage Policy and NCS 505: Denial of Coverage Policy Virginia Amendment. These guidelines provide steps in the medical necessity review, require the use of all information relevant to a member's care when making UM decisions, and require that denial determinations be made only by an appropriate clinical professional. NCQA UM 4 and MBHO UM 4, Appropriate Professionals, include requirements relating to the assessment of clinical information used to support UM decisions by qualified, licensed, health professionals. Additionally, professionals who review denials of care based on medical necessity must have education and experience in medical or clinical practice. NCQA UM 6 and MBHO UM 6, Clinical Information, require the use of all information relevant to a member's care when making UM decisions. If enough clinical information relevant to the medical necessity criteria is not provided with the

request, Aetna will attempt to obtain the clinical information needed to make a decision.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. This necessarily involves individualized evaluations and determinations for each member. A licensed clinician evaluates clinical coverage requests using the applicable guidelines. Clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. If the clinician cannot approve the request, it must be forwarded to a M/S or MH/SUD medical director or consultant psychiatrist, psychologist, or BCBA-D for review. While licensed clinical staff can issue M/S and MH/SUD coverage approvals, a medical director is responsible for any M/S and MH/SUD denial of coverage, including stating and documenting the rationale for any denial. Additional information relating to the process of making M/S and MH/SUD medical necessity determinations is included in Step 4, Part 2 below.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Individual needs of the member** are considered when clinical staff make coverage determinations using member-specific clinical information to determine whether the coverage request meets the applicable criteria/guidelines.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Aetna's clinical staff consider the individual needs of the member when applying the above criteria/guidelines in the medical necessity determination process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon in the application of this factor are NCQA Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, as implemented through Aetna's Policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment. These NCQA guidelines specify that at least the following characteristics be considered when applying M/S and MH/SUD clinical guidelines to each individual: 1) age; 2) comorbidities; 3) complications; 4) progress of treatment; 5) psychosocial situation; and 6) home environment, when applicable. Additionally, as required by NCS 503, Aetna clinical staff consider the individual's need for skilled care and risk related to ethnicity or genetic factors.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff, as described above in the preceding factor, draw upon their

training and expertise when reviewing the individual needs of the member and applying clinical criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. This necessarily involves individualized evaluations and determinations for each member. Additional information relating to the process of making M/S and MH/SUD medical necessity determinations is included in Step 4, Part 2 below.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **Characteristics of the local health care delivery system** means clinical staff consider the available services in the local health care delivery system and their ability to meet the member's specific health care needs in applying clinical criteria. The health care delivery system encompasses all the people, institutions, and services that contribute to care coordination, patient flows, diagnosis, disease management, and health maintenance programs.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Aetna's clinical staff consider characteristics of the local health care delivery system when applying the above criteria or guidelines in the medical necessity determination process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon in the application of this factor are NCQA UM Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, as implemented through Aetna Policy NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment. These NCQA guidelines provide for consideration of available services in the local delivery system and their ability to meet the member's specific health care needs, in the application of medical necessity guidelines. Aetna's policy NCS 503 details the components clinical staff consider, which apply to both M/S and MH/SUD reviews:

- Available services and their ability to meet the member's specific health care needs;
- The ability of the provider to meet the member's cultural and language needs, as appropriate;
- The availability of highly specialized services, such as detoxification facilities;
- The availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and,
- The ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the

estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff, as described in the preceding factor, draw upon their training and expertise when reviewing the characteristics of the local health care delivery system and applying clinical criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. This necessarily involves individualized evaluations and determinations for each member. Additional information relating to the process of making M/S and MH/SUD medical necessity determinations is included in Step 4, Part 2 below.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

Relationship, ordering, and weighting of multiple factors: The factors listed above apply equally to M/S and MH/SUD benefits. While applying Aetna's medical necessity criteria/guidelines described in subparts (a) and (b), Aetna's clinical staff apply their training, expertise, and clinical judgment to review all available, pertinent, member-specific information, which is used to consider the individual needs of the member and the characteristics of the local health care delivery system. No factor is weighted more heavily than the other. The factors are interrelated, and all operate together to ensure that Aetna employs an appropriate and effective medical necessity determination process.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, all M/S and MH/SUD covered services must be medically necessary. Accordingly, medical necessity applies to the following benefit classifications: 1) in-network inpatient; 2) out-of-network inpatient; 3) in-network office visit; 4) out-of-network office visit; 5) in-network outpatient–all other; 6) out-of-network outpatient–all other; and 7) emergency. As noted in Step 2, Part 1, the factors used in the design of Aetna's medical necessity programs are: 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, all of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. These general design factors are the basis and rationale underlying Aetna's policies and processes related to medical necessity. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, these factors apply equally to both benefit types.

Quality care and service to members, as defined in Step 2, Part 1, above, is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD benefits. As provided in **Aetna's UM Program Description**, applicable to both M/S and MH/SUD benefits, Aetna seeks to provide members with access to quality care and service while coordinating needed benefits. The UM Program Description supports Aetna's medical necessity review processes and details the accountability and structure of the committees responsible for reviewing, updating, and adopting the clinical criteria used in medical necessity reviews and the policies and procedures for applying clinical criteria. As explained above, each year, Aetna's NQAC reviews, and Aetna's NQOC adopts, Aetna's M/S and MH/SUD medical necessity criteria/guidelines, including both third-party guidelines and the Aetna CPBs. As written in the UM Program Description, the NQAC role includes "review of clinical criteria such as UM criteria, BH clinical criteria, Medical and BH Clinical Policy Bulletins (CPBs) and protocols for adoption by the NQOC." The role of the NQOC includes "adopting clinical criteria for both medical and behavioral health care and protocols with consideration of recommendations from the National Quality Advisory Committee (NQAC)." As set forth above, the NQAC is a multidisciplinary committee, which meets quarterly, and is comprised of external practitioners, including M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The purpose of the NQAC is to solicit feedback from Aetna's participating providers on various topics including M/S and MH/SUD medical necessity criteria. The NQOC, an Aetna body including representation of M/S and MH/SUD clinicians, considers the NQAC feedback and recommendations in adopting the M/S and MH/SUD medical necessity criteria. The factor of quality care and service to members, based upon evidentiary standards of NCQA UM Standards and NCQA MBHO UM Standards is further articulated through various Aetna National

Clinical Services policies which apply equally to M/S and MH/SUD benefits and are discussed in Step 4, Part 2 below.

Accordance with generally accepted standards of medical practice, as defined in Step 2, Part 1, is a general design factor that does not distinguish between, and is comparably applied to, both M/S and MH/SUD benefits. For M/S, the Virginia certificate of coverage defines generally accepted standards of medical practice as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and following the standards set forth in our clinical polices and applying clinical judgment, " and the MH/SUD definition further identifies the relevant medical community.

All M/S and MH/SUD medical necessity determinations are to be made in accordance with generally accepted standards of medical practice, pursuant to NCS 503: Medical Review Policy and Procedure and NCS 503: Medical Review Policy and Procedure Virginia Amendment. This factor is further articulated through the requirements for, and selection of, medical necessity guidelines used by Aetna clinicians conducting medical necessity reviews for M/S and MH/SUD services, as well as the process for conducting medical necessity reviews for M/S and MH/SUD services, implemented through NCS 503 and further discussed in Step 4, Part 2, below. In general, the following guidelines/criteria are considered to be in accordance with generally accepted standards of medical practice. However, for insured plans, applicable state law may require Aetna to apply an alternative criterion:

- MCG Health Care Guidelines
- National Comprehensive Cancer Network (NCCN) guidelines
- American Society of Addiction Medicine (ASAM) criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions*
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS)
- Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII)
- Aetna Applied Behavioral Analysis Medical Necessity Guide
- Aetna Clinical Policy Bulletins

Aetna's **UM Program Description** refers to each of the design factors, including cost management. The UM Program Description provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." Cost management as a design factor is further articulated in CVS Health public filings, which acknowledge that failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (*see, e.g.*, Form 10-K at page 34:

"Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). While these materials refer to the general design factors of promotion of cost management and clinically appropriate utilization, there is no written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of medical necessity with respect to M/S and MH/SUD benefits.

These design factors, 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, apply equally to both benefit types and are not applied incomparably, or more stringently, to MH/SUD benefits in the benefit classifications noted above. Similarly, there are no deviations or variations from these three factors, as they apply to the design of medical necessity. As written, the processes, strategies, evidentiary standards or other factors used in designing medical necessity with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing medical necessity with respect to M/S benefits across the applicable benefit classifications.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, medical necessity applies to the following benefit classifications: 1) in-network inpatient; 2) out-of-network inpatient; 3) in-network office visit; 4) out-of-network office visit; 5) in-network outpatient–all other; 6) out-of-network outpatient–all other; and 7) emergency. As noted in Step 2, Part 2, different factors are applied in the context of medical necessity for: (a) developing Aetna CPBs used in the medical necessity determination process; (b) selection of nationally recognized third-party clinical guidelines used in the medical necessity determination process; and (c) the process of making medical necessity determinations. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying medical necessity to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying medical necessity to M/S benefits in the applicable benefit classifications.

(a) Developing Aetna Clinical Policy Bulletins (CPBs) used in the medical necessity determination process

As set forth in Step 2, Part 2, the following factors are applied when developing CPBs: 1) the medical technology must have final approval from the appropriate governmental regulatory bodies; 2) the scientific evidence must permit conclusions concerning the effect of the medical technology on health outcomes; 3) the medical technology must improve the net health outcomes;

4) the medical technology must be as beneficial as any established alternatives; and 5) the improvement must be attainable outside the investigational settings. Each of these factors is documented in Aetna's Clinical Policy Council Charter, which applies, as written, equally to M/S and MH/SUD services. Importantly, Aetna maintains one written Clinical Policy Council Charter and one written policy, AETNQM-070547: Process for Review and Approval of Aetna Clinical Policy Bulletins, which apply equally to M/S and MH/SUD services.

As written in the **Clinical Policy Council Charter** and the **Process for Review and Approval of Aetna Clinical Policy Bulletins,** which apply equally to M/S and MH/SUD services, Aetna's CPC evaluates the safety, effectiveness, and appropriateness of medical technologies (i.e., medical and surgical procedures, devices, biological products, behavioral health interventions, and the organizational and supportive systems within which such care is provided) that may be eligible for coverage under Aetna medical plans. The Clinical Policy Council Charter defines the CPC structure, including both M/S and MH/SUD medical directors, among other representation. The CPC voting member roster is included in Appendix G. In making these determinations, the CPC will review and evaluate evidence in the peer-reviewed published medical literature, information from the U.S. Food and Drug Administration and other federal public health agencies, evidence-based guidelines from national medical professional organizations, and evidence-based evaluations by consensus panels and technology evaluation bodies. The CPC considers the factors, and their accompanying evidentiary standards and sources, listed in Step 2, Part 2, in determining whether a medical technology is medically necessary. All five criteria must be demonstrated in order for the CPC to deem a M/S or MH/SUD technology medically necessary. Those criteria, as set forth above, are:

- The medical technology must have final approval from the appropriate governmental regulatory bodies;
- The scientific evidence must permit conclusions concerning the effect of the medical technology on health outcomes;
- The medical technology must improve the net health outcomes;
- The medical technology must be as beneficial as any established alternatives; and
- The improvement must be attainable outside the investigational settings.

These documents further provide, as to the process for developing CPBs, that upon request and prior to consideration by the CPC, Aetna's Clinical Policy Research and Development Team evaluates and renders an opinion on the experimental, investigational, or unproven status and medical necessity of medical services or a technology that is considered for coverage under Aetna medical benefit plans. Requests usually come from Aetna's M/S and MH/SUD medical directors or other clinical staff in the context of preauthorization, precertification, or retrospective claim review. In developing M/S or MH/SUD CPBs, for each medical technology selected for evaluation, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews

relevant technology assessments indexed in the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database. In addition, the opinions of relevant experts may be obtained when necessary.

Both new and revised CPB drafts undergo a comprehensive review and vote by Aetna's CPC. Once promulgated, M/S and MH/SUD CPBs are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other relevant new information warrants more frequent review. In conducting this annual review, if the Clinical Policy Research and Development Team determines that new evidence or other information has emerged to warrant a change in Aetna's clinical policy, a revised CPB draft is prepared. If no new evidence has emerged that would warrant a change in Aetna's position, the CPB may be updated with additional supporting background information and references. Each revised M/S and MH/SUD CPB is submitted to Aetna's CPC for review and approval. The members of the CPC, or their designees, vote whether to recommend approval of each draft CPB. Additional changes to a revised or updated draft CPB may be made upon the recommendations of the CPC.

Approved M/S and MH/SUD CPBs are published on Aetna's websites within 60 days of the CPC's recommendations. Approved new, revised, and updated CPBs become effective when they are published on Aetna's CPB websites. A complete index of published CPBs can be found on Aetna's external CPB website[1]: Medical Clinical Policy Bulletins. The written policies pertaining to Aetna's CPBs discussed herein all apply equally to M/S and MH/SUD benefits. Aetna's analysis of the "as written" material used in the application of medical necessity to develop Aetna's CPBs used in the medical necessity determination process, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD benefits and not more stringently applied to MH/SUD benefits.

(b) Selection of nationally recognized third-party clinical guidelines used in the medical necessity determination process

As set forth in Step 2, Part 2, the factors for selection of nationally recognized third-party clinical guidelines used in the medical necessity determination process are: 1) the clinical criteria must be objective and based on medical evidence; 2) appropriate practitioners must be involved in developing, adopting, and reviewing criteria; and 3) applicable state law. These factors apply to medical necessity guidelines pertaining to both M/S and MH/SUD benefits, and are based on NCQA Standards and Guidelines for the Accreditation of Health Plans and Managed Behavioral Healthcare Organizations, as implemented through Aetna's UM Program Description and Aetna

[1] Available at https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/medical-clinical-policy-bulletins.html

Policy NCS 503: Medical Review Policy and Procedure. These written materials apply equally to M/S and MH/SUD benefits.

As required by NCQA and implemented through Aetna's **UM Program Description,** Aetna uses evidence-based clinical guidelines from nationally recognized authorities based on sound clinical evidence, backed by well-conducted clinical trials or cohort studies published in peer reviewed, evidence-based scientific literature in the medical necessity determination process, Aetna involves appropriate practitioners in developing, adopting, and reviewing medical necessity criteria through the NQAC and NQOC. As set forth above, the NQAC is a multidisciplinary committee, which meets quarterly, and is comprised of external practitioners, including M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The NQOC, which also includes M/S and MH/SUD clinical representation, considers the NQAC feedback and recommendations in adopting the M/S and MH/SUD medical necessity criteria.

NCS 503: Medical Review Policy & Procedure establishes the process of medical review and documents the written clinical criteria/guidelines adopted by the NQOC to be used by Aetna's clinicians in making medical necessity determinations for M/S and MH/SUD benefits, as further discussed in subpart (c). Regarding application of state law, as written in Aetna's UM Program Description, the NQOC approves state-specific amendments to the NCS policies to reflect the use of specific M/S and/or MH/SUD medical necessity guidelines as required by state law where applicable. These applicable state amendments are referenced in NCS 503.

The written policies pertaining to the selection of nationally recognized third-party clinical guidelines discussed herein all apply equally to M/S and MH/SUD benefits. Aetna's analysis of the "as written" material used in the application of medical necessity, to select nationally recognized third-party clinical guidelines used in the medical necessity determination process, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(c) The process of making medical necessity determinations

As set forth above in Step 2, Part 2, the factors used in application, for the process of making medical necessity determinations are 1) review of all available, pertinent, clinical information submitted as part of the coverage determination process by appropriate clinical professionals; 2) individual needs of the member; and 3) characteristics of the local health care delivery system. These processes are described in detail in the Aetna National Clinical Services (NCS) policies and procedures pertaining to medical necessity determinations. Aetna maintains one set of written policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to make medical necessity determinations for both M/S and MH/SUD services:

- NCS 503: Medical Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure Virginia Amendment
- NCS 505: Denial of Coverage Policy and Notification
- NCS 505: Denial of Coverage Policy and Notification Virginia Amendment
- NCS 506: Peer-to-Peer Review Policy
- NCS 506: Peer-to-Peer Review Policy Virginia Amendment
- NCS 510: Internal Quality Review Policy

Each of these policies is discussed in turn below, demonstrating that they support the factors outlined above and are comparably applied, as written, to M/S and MH/SUD services.

NCS 503: Medical Review Policy & Procedure establishes the process of medical review and documents the written clinical criteria/guidelines adopted by the NQOC, to be used by Aetna's clinicians in making medical necessity determinations. This policy applies equally to M/S and MH/SUD benefits. For both M/S and MH/SUD services, the clinical reviewers exercise their clinical judgment, guided by the written clinical criteria/guidelines, to make medical necessity determinations. While NCS 503 sets forth separate written guidelines that apply to M/S and MH/SUD services, all services are subject to appropriate guidelines based on industry standards and generally accepted standards of medical practice and clinical appropriateness, and these guidelines are reviewed and adopted annually by the NQOC as described in subpart (b). NCS 503 otherwise does not differentiate between M/S and MH/SUD services. The relevant specific written guidelines referred to in NCS 503, along with whether the guidelines apply to M/S services, MH/SUD services, or both, are:

- **LOCUS and CALOCUS/CASII** (MH/SUD): Aetna uses the most current versions of LOCUS and CALOCUS/CASII, which are recognized nationally as a generally accepted standard of care tool, to guide clinicians in making medically necessary level of care determinations for mental health services. The Level of Care Utilization System (LOCUS) assessment was developed by the American Association of Community Psychiatrists (AACP) in 1996 to help determine the mental health care resource intensity needs of adults. CALOCUS was developed was developed by the American Association of Community Psychiatrists in collaboration with the American Association of Child and Adolescent Psychiatry to help determine the mental health care resource intensity needs of children and adolescents.

- **ASAM** (MH/SUD): Aetna uses the most current criteria published by the American Society of Addiction Medicine (ASAM) to guide clinicians in evaluating the medical necessity of levels and types of care for substance use disorders. ASAM criteria are generally accepted, national standards for SUD treatment decisions and are recognized as such by many courts and regulators.

- **ABA Medical Necessity Guide** (MH/SUD): Aetna's ABA medical necessity guidelines come from extensive review of the literature on the use of applied behavior analysis to treat autism spectrum disorder and a comparative review of the guidelines of other health insurers. A multidisciplinary committee of health care professionals within and external to Aetna Behavioral Health developed and approved the guidelines based on these reviews.

- **MCG Health Care Guidelines** (M/S): Aetna uses the most current evidence-based Care Guidelines published by MCG Health to guide clinicians in making medically necessary level of care determinations for M/S services.

- **Aetna Clinical Policy Bulletins (CPBs)** (M/S and MH/SUD): CPBs are written on selected clinical issues, especially addressing new medical technologies such as devices, drugs, procedures, and techniques. CPBs are continually reviewed and updated to reflect current information, as described in subpart (a).

- **NCCN Clinical Practice Guidelines in Oncology** (M/S): Aetna uses the most current clinical practice guidelines published by the National Comprehensive Cancer Network (NCCN) to make medical necessity determinations in oncology clinical reviews. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are comprised of recommendations for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines currently apply to more than 97% of cancers affecting patients in the United States.

These guidelines do not replace professional judgment exercised by properly trained, licensed, and experienced clinicians and professionals who evaluate the provision of services in accordance with accepted standards of care. As explained in NCS 503, each individual M/S and MH/SUD medical necessity determination is afforded independent clinical consideration based on the member's presentation. In accordance with NCS 503, UM clinicians consider the individual needs of the member when utilizing guidelines, including, but not limited to age, co-morbidities, complications, progress of treatment, need for skilled care, psychosocial situation, risk related to ethnicity or genetic factors and home environment, when applicable. UM clinicians additionally consider the following characteristics of the local health care delivery system during the coverage determination process: the ability of the provider to meet the member's cultural and language needs, as appropriate; the availability of highly specialized services, such as detoxification facilities; the availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and, the ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition. NCS 503 further

notes that approval decisions may be automated when appropriate. Automation uses clinical information submitted by the provider and compares it to Aetna's clinical policies to render an approval decision, based on individualized clinical considerations, using the medical necessity guidelines outlined in NCS 503. For both M/S and MH/SUD medical necessity reviews, all adverse decisions are made by medical directors, never by automation or clinical staff who are not medical directors, as required by NCS 505: National Clinical Services Denial of Coverage Policy, discussed below. Thus, the "as written" material contained in NCS 503 pertaining to the medical review process is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 503 Medical Review Policy & Procedure Virginia Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 503, Medical Review Policy & Procedure. This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.

Additionally, **NCS 505** defines and outlines the handling of denial of coverage determinations, including the responsibility for issuing clinical and administrative denial decisions, documentation requirements for denial decisions and notification requirements for these coverage decisions. As written, this policy applies equally to M/S and MH/SUD services, and specifies that only M/S and MH/SUD medical directors can deny clinical coverage decisions. Because the processes are the same, the "as written" material contained in NCS 505 pertaining to the handling of coverage determination denials is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 505 Virginia Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 505 and will be used in conjunction with NCS 505 to comply with Virginia requirements.

NCS 506 outlines the peer-to-peer review process through which a treating practitioner, a clinician on behalf of the treating practitioner (e.g., genetic counselor for BRCA precertification requests) or a physician on behalf of a facility (for precertification denials) may request a discussion with a peer reviewer (licensed health plan physician medical director) or behavioral health consultant psychiatrist/psychologist/board certified behavior analyst-doctoral (BCBA-D), to discuss a clinical denial of coverage determination. Peer-to-peer is not an additional level of review or an appeal. It is a focused discussion between the provider representative and the peer reviewer. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D considers all available information when conducting a peer-to-peer review. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D reviews the applicable clinical criteria/guidelines in NCS 503, the clinical information that is present before and during the peer-to-peer discussion and uses clinical judgment to make a decision. For M/S, peer-to-peer reviews are conducted after a denial determination, upon request. For MH/SUD services, when clinically appropriate, peer-to-peer reviews are offered and conducted prior to the issuance of the initial

coverage determination, in addition to peer-to-peer reviews that are available after a denial determination. As written, the process for peer-to-peer review is largely the same for M/S and MH/SUD, except that for MH/SUD services, Aetna may offer a peer-to-peer review before a determination has been issued, in addition to the peer-to-peer review that is available post-determination. Based upon the foregoing, the written material contained in NCS 506 pertaining to peer-to-peer review is comparably applied to MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 506 Virginia Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 506 and will be used in conjunction with NCS 506 to comply with Virginia requirements.

Finally, **NCS 510** describes Aetna's Internal Quality Review and Inter-Rater Reliability assessments. As written, the quality review process provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. Through inter-rater reliability (IRR) assessments, both M/S and MH/SUD medical directors and Utilization Management clinicians are audited for accuracy and consistency in their application of utilization management criteria, and corrective actions are taken if the results do not meet certain metrics, which are the same for MH/SUD and M/S services. NCS 510 applies equally to M/S and MH/SUD services, and the processes set forth therein are the same for M/S and MH/SUD services. The "as written" processes in NCS 510, for evaluation of medical director and utilization management clinician accuracy and consistency, are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services.

The factors of 1) review of all available, pertinent, clinical information by appropriate clinical professionals; 2) individual needs of the member; and 3) characteristics of the local health care delivery system are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently, as written, to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the process of performing medical necessity reviews for M/S and MH/SUD services. The factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material pertaining to the medical necessity review process shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services than to M/S services.

Aetna provides members with appeal rights when an adverse benefit determination is issued. When Aetna issues a denial of services or a reduction in coverage due to a medical necessity determination, that determination is considered an adverse benefit determination. Members have the right to request a review of that determination through the appeal process and may initiate an appeal by contacting Aetna.

Appeal rights and procedures are described in the COC under the section titled "Appeal of an Adverse Benefit Determination." The COC outlines the appeal process, including applicable timeframes, who may request an appeal on behalf of the member, how appeals are assigned and reviewed, and the options available if the member is not satisfied with the appeal decision. Aetna does not maintain separate appeal processes for MH/SUD services and M/S services; the same appeal procedures apply to both. In addition, once the internal appeal process has been exhausted, members may have the right to request an external review, as described in the COC. The COC also explains the circumstances under which external review may be available and the procedures for requesting it. The appeal and external review rights available to members are applied consistently for MH/SUD and M/S services and are not more stringent for MH/SUD services than for M/S services.

Summary

The factors for developing CPBs, selection of nationally recognized third-party clinical guidelines, and the process of making medical necessity determinations, and the written materials relating to the same, apply equally to M/S and MH/SUD services. As written, the processes, strategies, evidentiary standards and other factors used in applying medical necessity to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying medical necessity to M/S benefits across the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

As noted in the guidance provided by the Bureau on July 6, 2026, “The BOI will not require an in-operation assessment for the medical necessity NQTL, as medical necessity is operationalized as part of the NQTLs of prior authorization, concurrent review, and retrospective review.”

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As noted in Step 1, all M/S and MH/SUD covered services must be medically necessary. Accordingly, medical necessity applies to the following benefit classifications: 1) in-network inpatient; 2) out-of-network inpatient; 3) in-network office visit; 4) out-of-network office visit; 5) in-network outpatient–all other; 6) out-of-network outpatient–all other; and 7) emergency. Step 2 identified the factors that are used to 1) develop Aetna CPBs used in the medical necessity determination process; 2) select nationally recognized third-party clinical guidelines used in the medical necessity determination process; and 3) make medical necessity determinations. Step 3 explained the evidentiary standards and sources for those factors, and how they are used in the design and application of medical necessity. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD services. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD services and concluded that there are no written differences in that application that results in any MH/SUD services being treated more stringently than, or incomparably to, M/S services.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, the factors used in the design of medical necessity are: 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, all of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Aetna maintains one UM Program Description, which is equally applicable to M/S and MH/SUD benefits, that sets forth the focus and goals of Aetna's utilization

management program. The focus and goals align to the three general design factors, which provide a basis and rationale underlying Aetna's policies related to medical necessity for M/S and MH/SUD services. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In the application of medical necessity, Aetna maintains one set of written policies pertaining to development of CPBs, selection of nationally recognized third-party guidelines, and conducting medical necessity review, that are equally applicable to M/S and MH/SUD services. Aetna applies the same factors, evidentiary standards, and sources, the same Process for Review and Approval of Clinical Policy Bulletins and the same Clinical Policy Charter to develop CPBs, and the same process to adopt nationally recognized third-party medical necessity guidelines for M/S and MH/SUD services. In addition, the same factors, evidentiary standards and sources, and the same National Clinical Services policies apply to conducting medical necessity reviews for M/S and MH/SUD services.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply medical necessity to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying medical necessity with respect to M/S benefits across the applicable benefit classifications. The factors, evidentiary standards and sources used to develop and adopt medical necessity criteria, and to actually conduct medical necessity reviews, are designed and applied in a comparable, and not more stringent manner, for MH/SUD benefits. Taken together with the favorable outcomes for MH/SUD at the book of business level, the medical necessity NQTL is designed and applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Executive Director, National Quality Management, Medical Doctor in General Practice • Sr. Clinical Solutions Medical Director, board certified in Internal Medicine • Behavioral Health Medical Director, Quality and Mental Health Parity, Medical Doctor board certified in Psychiatry • Behavioral Health Senior Medical Director, Quality, Medical Doctor board certified in Psychiatry • Sr. Manager, Health Care Quality, RN, BSN, MA, CPHQ

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Nonquantitative Treatment Limitation Comparative Analysis:

PRECERTIFICATION (aka PRIOR AUTHORIZATION) – IN-NETWORK

This Comparative Analysis consists of two separate analyses for precertification regarding: 1) in-network benefits and 2) out-of-network benefits.

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of precertification, and* ***(2)*** *an identification of all* ***in-network*** *mental health/substance use disorder (MH/SUD) and medical/surgical (M/S) benefits to which precertification applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: *In-Network* Precertification [45 CFR 146.137(c)(1)(i)]

Precertification is a pre-service utilization review performed by licensed healthcare professionals to determine medical necessity and appropriateness of treatment for certain covered services (identified in Part 2 below). Ultimately, this review will inform whether those covered services are eligible for payment under the terms of the health benefit plan. This is considered a clinical review form of prior authorization. Aetna does not conduct other forms of prior authorization. As set forth herein, precertification applies to M/S and MH/SUD inpatient admissions and certain M/S and MH/SUD outpatient services. The following materials describe in-network precertification:

1. **Plan Documents**

Virginia ALIC standard certificate of coverage provides:

Certificate of Coverage – VA AL HCOC 14

Medical necessity[, referral, and, precertification] requirements

Medically necessary, medical necessity

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

Precertification

You need pre-approval from us for some covered services. Pre-approval is also called precertification.

[In-network
Your network **[physician]** or **[PCP]** is responsible for obtaining any necessary **precertification** before you get the care. There is someone available to help your [**physician]** or [**PCP**] 24 hours a day. **Network [providers]** cannot bill you if they fail to ask us for **precertification**. But if your **[physician]** or **[PCP]** requests **precertification** and we deny it, and you still choose to get the care, you will have to pay for it yourself.]

[Timeframes for **precertification** are listed below. For **emergency services**, including an emergency inter-**hospital** transfer of a newborn with a life-threatening condition and for the mother to accompany the newborn, **precertification** is not required, but you should still notify us as shown.

To obtain **precertification**, contact us. You, your **[physician]** or the facility must call us within these timelines:

Type of care	Timeframe
Non-emergency admission	Call at least [14 days] before the date you are scheduled to be admitted
Emergency admission	Call within [48 hours] or as soon as reasonably possible after you have been admitted
Urgent admission	Call before you are scheduled to be admitted
Outpatient non-emergency medical services	Call at least [14 days] before the care is provided, or the treatment or procedure is scheduled

An urgent admission is a **hospital** admission by a **[physician]** due to the onset of or change in an illness, the diagnosis of an illness, or injury.

We will tell you and your **[physician]** in writing of the **precertification** decision, where required by state law. An approval is valid for [30-180 days] as long as you remain enrolled in the plan.

For an inpatient **stay** in a facility, we will tell you, your **[physician]**, and the facility about your **precertified** length of **stay**. If your **[physician]** recommends that you stay longer, the extra days will need to be **precertified**. You, your **[physician]**, or the facility will need to call us as soon as reasonably possible, but no later than the final authorized day. We will tell you and your **[physician]** in writing of an approval or denial of the extra days.

If you or your **[provider]** request **precertification** and we don't approve coverage, we will tell you why and explain how you or your **[provider]** may request review of our decision. See the Complaints, claim decisions and appeal procedures section.]

Types of services that require precertification

Precertification is required for inpatient **stays** and certain outpatient services and supplies.

[Precertification is required for the following types of services and supplies:
[Inpatient –

- [Gender affirming treatment]
- [Gene-based, cellular and other innovative therapies (GCIT)]
- [Obesity (bariatric) **surgery]**
- **Stays** in a hospice facility
- **Stays** in a **hospital**
- **Stays** in a rehabilitation facility
- **Stays** in a **residential treatment facility** for treatment of **mental health disorders** and **substance use disorders**
- **Stays** in a **skilled nursing facility**]

[Outpatient –

- [Applied behavior analysis]
- [ART services]
- Complex imaging
- Cosmetic and reconstructive **surgery**
- [Gender affirming treatment]
- [Gene-based, cellular and other innovative therapies (GCIT)]
- [Home health care]
- Hospice care
- Injectables, (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications)
- Kidney dialysis
- Knee **surgery**
- [Limited infertility services]
- Non-emergency transportation by airplane
- [Obesity (bariatric) **surgery]**
- Outpatient back **surgery** not performed in a **[physician's]** office
- Partial hospitalization treatment – **mental health disorders** and **substance use disorders** treatment
- [Private duty nursing services]
- Sleep studies
- Transcranial magnetic stimulation (TMS)
- Wrist **surgery**]

Contact us to get a complete list of the services that require **precertification**. The list may change from time to time.]

Sometimes you or your **[provider]** may want us to review a service that doesn't require **precertification** before you get care. This is called a predetermination, and it is different from **precertification**. Predetermination means that you or your **[provider]** requests the pre-service clinical review of a service that does not require **precertification**.

Glossary Definition

Medically necessary, medical necessity (mental health or substance use disorder)

A service or product addressing the specific needs of a patient for the purpose of screening, preventing, diagnosing, managing, or treating such disorder, including:

- Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care
- Clinically appropriate in terms of type, frequency, extent, site, and duration
- Not defined primarily for the economic benefit of an insurer or purchaser or for the convenience of the patient, treating physician, or other health care provider.

Generally accepted standards of mental health or substance use disorder care means evidence-based independent standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment. Sources reflecting "generally accepted standards of mental health or substance use disorder care" include:

- Peer-reviewed scientific studies and medical literature
- Consensus guidelines and recommendations of nonprofit health care provider professional associations and specialty societies
- Nationally recognized clinical practice guidelines, including:
  - Patient placement criteria
  - Service intensity assessment instruments
  - Clinical practice guidelines
  - Guidelines and recommendations of federal government agencies
  - Drug labeling approved by the U.S. Food and Drug Administration

Important note:
We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Medically necessary, medical necessity (other than mental health or substance use disorder)

Health care services or supplies that prevent, evaluate, diagnose or treat an illness, injury, disease or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with “generally accepted standards of medical practice”
- Clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease

- Not primarily for your convenience, the convenience of your **[physician]**, or other health care **[provider]**
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your illness, injury or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and
- Following the standards set forth in our clinical policies and applying clinical judgment

Important note:
We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Precertification, precertify

Pre-approval that you or your provider receives from us before you receive certain covered services.

2. Provider Contracts

Aetna's template provider contract for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to precertification. The same template provider contract is used for both M/S and MH/SUD providers. Specifically, under "Provider obligations," the template contract states: "Provider agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Provider agrees to comply with Company Policies, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria; Provider Manuals; clinical policy bulletins; credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, complaint and appeals, and other policies and procedures (as modified from time to time), that are made available to Provider electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

3. Facility Contracts

In addition, Aetna's template facility contract sets forth the obligations of Aetna's participating facilities with respect to precertification. The same template contract is used for both M/S and MH/SUD providers. The contract provides "Facility agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Facility agrees to comply with Company Policies of which Facility knows or reasonably should have known, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria, Provider Manuals, clinical policy bulletins, credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, Institutes of Excellence™, complaint and appeals, and other policies and procedures (as modified from time to time) that are made available to Facility electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

Additionally, under "Facility Obligations," the template contract states:

> Utilization Management. Facility agrees that it shall be subject to utilization management (including prospective, concurrent and retrospective review) and that payment for Facility services may be adjusted or denied for the inefficient delivery of services related to admissions, or length of stay. To facilitate timely and accurate concurrent utilization management, Facility and Company will cooperate as necessary to facilitate on-site and/or concurrent telephonic utilization management at Facility.
>
> Precertification and Referrals. Except when a Member requires emergency services, Facility agrees to comply with any applicable precertification and/or referral requirements under the Member's Plan prior to the provision of Facility services. Facility will utilize the electronic real time HIPAA compliant transactions, including but not limited to, eligibility, precertification and claim status inquiry transactions. Facility agrees to provide notice of all admissions of Members, and of all services for which Company requires notice, upon admission or prior to the provision of such services. For the purpose of pre-admission testing, Facility agrees to directly provide testing or accept test results and examinations performed outside Facility, provided such tests and examinations are: (a) performed by a state licensed laboratory for laboratory tests, and a licensed physician for such other tests and examinations; and (b) performed within a time reasonably proximate to the admission. For those Members who require services under a specialty program, Facility agrees to work with Company in transferring the Member's care to a specialty program Facility, as the case may be.

4. Provider Manual

These requirements are also referenced in Aetna's Provider Manual, applicable to participating providers. Please see Appendix A for the Provider Manual provisions applicable to precertification.

5. Policies and Procedures

The following internal policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address precertification:

- **National Precertification List P&P** – Aetna's policy for maintaining a consistent precertification list that participating physicians, hospitals, and other health care professionals can use to determine when precertification is required for Aetna products and plans.
- **NCS 100: Precertification P&P** – Aetna's policy defining precertification and providing the rules and processes for applying clinical criteria/guidelines to covered benefits for eligible members during the pre-service review process.
- **NCS 503: Medical Review P&P** – Aetna's policy that explains the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
    - **National Clinical Services (NCS) 503 Medical Review – Virginia**
        - This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
- **NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy** – Aetna's policy outlining the timeliness standards for notifying members/providers of coverage decisions.
    - **National Clinical Services (NCS) 504 Timeliness Standards for Coverage Decisions and Notification Policy - Virginia**
        - This amendment will be used in conjunction with NCS 504 to comply with Virginia requirements.
- **NCS 505: Denial of Coverage Policy and Notification** – Aetna's policy defining and outlining the handling of denial of coverage determinations.
    - **National Clinical Services NCS 505: Denial of Coverage Policy and Notification – Virginia**
        - This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements.
- **NCS 506: Peer-to-Peer Review Policy** – Aetna's policy that describes the process for treating practitioners/clinicians/physicians to discuss a clinical denial with a peer reviewer or behavioral health consultant/psychiatrist/psychologist.
    - **National Clinical Services NCS 506: Peer-to-Peer Review – Virginia**
        - This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.
- **NCS 510: Internal Quality Review Policy** – Aetna policy describing the internal quality review process to assess the compliance with policies and procedures for individuals who support the health plan's medical management programs.

Additionally, Aetna's Care Management Program Description ("**UM Program Description**"), which applies to M/S and MH/SUD benefits, encompasses Aetna's utilization management program. The UM Program Description defines the scope, goals and objectives, processes, and monitoring of precertification and other utilization management programs.

Aetna maintains a comprehensive vendor oversight program applicable to all third-party entities that perform functions related to the administration of covered benefits. Under this program, vendors are contractually required to operate in accordance with Aetna's policies, procedures, clinical guidelines, and oversight requirements, regardless of whether the services provided relate to benefits or MH/SUD benefits. Aetna utilizes Evicore to perform certain clinical administrative functions, including precertification and prior authorization review activities. Aetna approves vendor criteria through Utilization Management committees and clinical policy review. Our vendors services support the administration of both M/S and MH/SUD benefits, as applicable.

There are no separate vendor-specific prior authorization requirements, evidentiary standards, or decision-making frameworks used by our vendors for MH/SUD benefits versus M/S benefits. Prior authorization determinations conducted by our vendors are made in accordance with Aetna utilization management policies, clinical guidelines, and operational procedures applicable to the benefit being reviewed. Aetna retains responsibility for oversight of vendor performance and compliance with contractual obligations, regulatory requirements, and applicable Aetna standards. Through its ongoing governance and monitoring processes, Aetna evaluates vendor operations to ensure that utilization management activities, including prior authorization reviews, are administered consistently with Aetna's policies and procedures for both MH/SUD and M/S benefits.

Overview

For in-network benefits, precertification applies to inpatient admissions and select ambulatory procedures and services. Precertification applies to 1) services on the Aetna Participating Provider Precertification List, 2) services on the Aetna Behavioral Health Precertification List, and 3) any other services that require precertification under the terms of the member's plan.

The Aetna Participating Provider Precertification List and Aetna Behavioral Health Precertification List are referred to collectively as the National Precertification List (NPL). The most current versions are publicly available at aetna.com/health-care-professionals/precertification/precertification-lists.html

Benefits and Classification

Precertification applies to M/S and MH/SUD benefits in the following benefit classifications, as set forth below: **in-network inpatient**; **in-network outpatient–all other**.

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **INN OP AO**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
INN Inpatient All inpatient admissions including hospital at home, skilled nursing facilities and rehabilitation facilities (except hospice and maternity/newborn stays within the standard length of stay)	**INN Inpatient** All inpatient admissions including residential treatment facilities
INN Outpatient – All Other Too numerous to list – see the National Precertification List	**INN Outpatient – All Other** • Applied Behavioral Analysis (ABA) for Autism Spectrum Disorder • Partial Hospitalization (PHP) • Transcranial Magnetic Stimulation • Gender Affirmation Surgery

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of precertification. Each subpart includes,* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to precertification, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL.

Factor	Applicable to M/S	Applicable to MH/SUD
Cost management	✓	✓

Clinically appropriate utilization	✓	✓

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

- **Clinically appropriate utilization** is a **factor** that seeks to ensure that M/S and MH/SUD treatments, procedures, or services are appropriate for the diagnosis, severity of illness, and overall health status of a patient, and that they are provided in accordance with clinically appropriate evidence-based guidelines and practices that are relevant to the condition being treated and that avoids misuse of care.
- In accordance with Virginia's standard certificate of coverage, for M/S services to be medically necessary, they should be "In accordance with generally accepted standards of medical practice, clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease". Medical necessity is comparably described in the COC for MH/SUD services as "Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care and considered clinically appropriate in terms of type, frequency, extent, site, and duration."

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) determining services subject to precertification - inpatient; (b) determining services subject to precertification - outpatient: adding a service to the National Precertification List (NPL); (c) determining services subject to precertification - outpatient: retaining a service on the NPL; and (d) the process for precertifying services (inpatient and outpatient).

(a) Factors for determining services subject to precertification – Inpatient

Factor	Applicable to M/S	Applicable to MH/SUD

Place of service	✓	✓
Federal law	✓	✓

- **Place of service** is a **factor** used to evaluate whether services are subject to a precertification requirement. Place of service refers to an inpatient admission to a hospital or other healthcare facility (e.g. skilled nursing facility, rehabilitation facility, or residential treatment facility), usually requiring an overnight stay and including room, board, and general nursing care. The **evidentiary standards and sources** upon which this factor is based are:
    - All inpatient admissions, except maternity/newborn admissions within the standard length of stay and hospice for both M/S and MH/SUD conditions, are subject to precertification.
    - Place of service is determined based on the bill classification identified on the facility claim submission.

- **Federal law** consists of regulatory and legal requirements concerning precertification requirements for inpatient services. The **evidentiary standards and sources** upon which this factor is based are:
    - Applicable federal laws and regulations, specifically, the federal Newborns' and Mothers' Health Protection Act (NMHPA) of 1996 which sets minimum length of stay requirements for maternity hospital stays and prohibits insurers from requiring authorization.

(b) Determining services subject to precertification – Outpatient: factors for adding a service to the NPL

Factor	Applicable to M/S	Applicable to MH/SUD
Cost of treatment	✓	✓
High-cost growth	✓	✓
Variability in cost and practice	✓	✓
Return on investment	✓	✓

- **Cost of treatment** is the measurement of the cost of an M/S or MH/SUD service. The **evidentiary standards and sources** upon which this factor is based are:
    - The average Medicare rate of at least $150, meaning that a service may be added to the NPL if its average Medicare rate is at least that amount.
    - Aetna's national paid Medicare claims experience.

- **High-cost growth** is the measurement of material and sustained increase in the expenses associated with providing covered M/S and MH/SUD services. The **evidentiary standards and sources** upon which this factor is based are:
    - The per member per month expense for the service. If that expense for a service increases more than 10% in the most recent two-year period compared to an initial baseline, the service may be added to the NPL.
    - Internal Aetna claims data for M/S and MH/SUD services.
- **Variability in cost and practice** is the measurement of variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period. The **evidentiary standards and sources** upon which this factor is based are:
    - Claims data that demonstrates a greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment.
    - Internal Aetna claims data for M/S and MH/SUD services.

- **Return on Investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs. The **evidentiary standard and sources** upon which this factor is based are:
    - Forecasted ROI of at least 3:1.
    - A calculation based on internal claims data and administrative cost data: (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service.

The following **extenuating factors** may also be considered for adding a service to the NPL:

Factor	Applicable to M/S	Applicable to MH/SUD
Patient safety	✓	✓
Clinical quality control	✓	✓
Marked variation in provider utilization patterns	✓	✓
Incorrect utilization	✓	✓
Application of Clinical Policy Bulletins	✓	✓
Standards of industry practice	✓	✓

- **Patient safety** refers to whether precertification can minimize potential harm to a member, particularly for life changing procedures that are irreversible post-surgery. The **evidentiary standards and sources** upon which this factor is based are:

- Evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
- The most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found in various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

- **Clinical quality control** refers to efforts to verify that a provider and proposed treatment are qualified and appropriate so that the possibility of adverse outcomes is reduced. The **evidentiary standards and sources** upon which this factor is based are:
  - Evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
  - The most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

- **Marked variation in provider utilization patterns** means the existence of a significant range in providers' utilization of the service, drug or device, suggesting that some of the utilization may be unnecessary. The **evidentiary standards and sources** upon which this factor is based are:
  - The review of trends in provider utilization patterns and procedure codes for services that providers furnish, and how those trends align with clinical guidelines.
  - Utilization as a company, competitor information, and vendor input.

- **Incorrect utilization** means the potential that a given service, drug or device is not appropriate for the member's condition. The **evidentiary standards and sources** upon which this factor is based are:

- Evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
- The most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

- **Application of Clinical Policy Bulletins (CPB)** refers to the opportunity to make determinations required under Aetna's CPBs and other clinical policies pertaining to the experimental, investigational, or unproven nature of a service, appropriate use of new or changing technology, step therapy, or site of service. The **evidentiary standards and sources** upon which this factor is based are:
  - The large number of analyses and conclusions contained within the CPBs.
  - Evidence-based and peer reviewed literature referenced within said CPBs.

- **Standards of industry practice** are what other health insurers and administrators have decided to be appropriate in terms of precertification. The **evidentiary standards and sources** upon which this factor is based are:
  - Publicly available information from competitors and public health organizations such as the Centers for Disease Control and Prevention (CDC) and U.S. Department of Health and Human Services (HHS).
  - Competitor analysis to determine whether precertification is appropriate for a given service at a given time (e.g. during a public health emergency).

(c) Factor for determining services subject to precertification – Outpatient: retaining a service on the NPL

Factor	Applicable to M/S	Applicable to MH/SUD
Return on investment	✓	✓

- **Return on investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs. The **evidentiary standard and sources** upon which this factor is based are:

- Actual ROI of at least 3:1.
- A calculation based on internal claims data and administrative cost data (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service.

While ROI is the primary factor used to determine retention of an M/S or MH/SUD service on the NPL, the extenuating factors described above in (b) may also be considered.

(d) Factors for the process of precertifying services (inpatient and outpatient services)

Factor	Applicable to M/S	Applicable to MH/SUD
NCQA Guidelines and Standards	✓	✓
Generally accepted standards of medical practice and clinical appropriateness	✓	✓
Applicable state and federal law	✓	✓

- **National Committee for Quality Assurance (NCQA) Accreditation Standards -** NCQA sets utilization management standards for Health Plan accreditation and Managed Behavioral Health Organization accreditation. The **evidentiary standards and sources** upon which this factor is based are:
  - Timeliness and clinical review standards that Aetna sets to meet NCQA Guidelines and Standards, as implemented through Aetna policies NCS 503: Medical Review P&P and NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P and applicable VA amendments.
  - NCQA Health Plan Accreditation and MBHO Utilization Management Standards and Guidelines: Clinical Criteria for UM Decisions, Appropriate Professionals, Timeliness of UM Decisions, and Clinical Information.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in our clinical policies. In general, the following **sources** contain the **evidentiary standards** (i.e., clinical treatment guidelines) utilized by Aetna's clinicians during the precertification determination process:
  - Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
  - MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
  - National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)

- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

- **Applicable state and federal law** are regulatory and legal requirements concerning the precertification process. The **evidentiary standards and sources** upon which this factor is based are:
  - Time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations, as implemented through Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P.
  - Timeframes set forth in applicable state law for insured plans, that require certain turnaround times for precertification decisions in some states. State law or regulation that mandates a more stringent response time supersedes Aetna's national standard, and are acknowledged in state amendments to the corresponding NCS P&Ps.
  - Specific medical necessity guidelines set forth in applicable law. Insured plans in a state that requires use of specific medical necessity guidelines are administered in accordance with the state's requirements, and are acknowledged in state amendments to the corresponding NCS P&Ps.
  - Other applicable state law requirements pertaining to precertification.

Step 3: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Cost management** is a factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management applies equally to all M/S and MH/SUD benefits. Cost management generally underlies Aetna's determination that M/S and MH/SUD inpatient services require precertification. For M/S and MH/SUD outpatient services subject to a precertification requirement, cost management aligns directly to the terms "cost," "high-cost growth," "variability in cost and practice," and "ROI" defined and identified above in Step 2 and more fully below in Step 3, Part 2.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: With respect to cost management, the evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. Since Aetna's entrance into the insurance and health plan administration business, cost management has been and continues to be a significant operating consideration. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (*see, e.g.,* Form 10-K at page 34 "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through **. . .**

medical management programs."). This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of precertification, cost management does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

- **Clinically appropriate utilization** is a factor and strategy underlying the design of precertification, seeking to ensure the plan covers medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In accordance with Virgnia's standard certificate of coverage, medically necessary health care services are those that are clinically appropriate in terms of type, frequency, extent, site, place of service, duration, and considered effective for the member's illness, injury, or disease.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of clinically appropriate utilization applies equally to all M/S and MH/SUD benefits. This design factor aligns to the use of uniform evidentiary standards to assess the clinical appropriateness of a particular service, discussed in more detail below.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards considered and relied upon when designing this NQTL are those generally accepted standards of care identified above in Step 2, Part 1 (e.g., MCG, LOCUS, CALOCUS). For M/S benefits, the assessment of whether care is clinically appropriate in the context of precertification relies on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. For MH/SUD benefits, clinically appropriate utilization is based on the American Society of Addiction Medicine (ASAM) Criteria: *Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), Aetna's Applied Behavioral Analysis Medical Necessity Guide, and the appropriate Aetna MH/SUD Clinical Policy Bulletins. Please see Aetna's Medical Necessity NQTL Comparative Analysis for a detailed analysis of the factors, evidentiary standards and sources relied upon to adopt Aetna's medical necessity criteria.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of precertification, clinically appropriate utilization does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of clinically appropriate utilization, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of cost management and clinically appropriate utilization apply equally and agnostically to both M/S and MH/SUD benefits in the general design of precertification. They are interrelated because they collectively seek to ensure that the plan covers only medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors, as they are considered equally important for an effective precertification process. Similarly, no one factor is weighted more than another in the design of precertification.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in the application of precertification for: (a) determining services subject to precertification- inpatient; (b) determining services subject to precertification- outpatient: adding a service to the NPL, (c) determining services subject to precertification- outpatient: retaining a service on the NPL, and (d) for those services for which precertification is required, the process for precertifying services (inpatient and outpatient).

(a) Determining services subject to precertification – Inpatient

- **Place of service** refers to an inpatient admission to a hospital or other healthcare facility (e.g., skilled nursing facility, rehabilitation facility, or residential treatment facility), usually requiring an overnight stay and including room, board, and general nursing care.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Where a service has an inpatient place of service, precertification is required, except for the limited circumstances addressed below. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: Place of service is established upon admission to a facility; inpatient admissions as identified by the type of bill code on the claim submission require precertification. The type of bill is a 4-digit code on the UB-04 claim form, as specified by the National Uniform Billing Committee (NUBC). Inpatient claims are identified as:

i. 011x – Inpatient Hospital
ii. 021x – Inpatient Skilled Nursing Facility
iii. 0115 – Hospice Room and Board – Private

iv. 0125 – Hospice Room & Board – Semi-private

Revenue codes are used for MH/SUD inpatient claims. The NUBC also defines and maintains these:

v. 100x – Behavioral Health Accommodations
vi. 1000 – Behavioral Health Accommodations-General
vii. 1001 – Behavioral Health Accommodations-Residential Psychiatric
viii. 1002 – Behavioral Health Accommodations-Residential Chemical Dependency
ix. 1003 – Behavioral Health Accommodations-Supervised Living
x. 1004 – Behavioral Health Accommodations-Halfway House
xi. 1005 – Behavioral Health Accommodations-Group Home

This standard applies equally to M/S and MH/SUD benefits. Claims identified as inpatient hospice, for both M/S and MH/SUD conditions, are not subject to precertification.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to inpatient MH/SUD and M/S benefits.

- **Federal law** consists of regulatory and legal requirements concerning precertification requirements for inpatient services.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Where applicable federal law would prohibit Aetna from requiring precertification for an inpatient stay, Aetna complies with the applicable legal requirements and does not require precertification. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** In this context, the applicable evidentiary standard is the NMHPA, which sets minimum length of stay requirements for maternity hospital stays. Pursuant to the NMHPA, a health plan must provide inpatient maternity coverage for a mother and her newborn child for a minimum of 48 hours (2 days) following a normal vaginal delivery, and a minimum of 96 hours (4 days) following a Cesarean section delivery. The health plan cannot require the attending physician to obtain authorization from the plan for prescribing the 48/96-hour minimum stay.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to inpatient MH/SUD and M/S benefits.

***Relationship, ordering, and weighting of multiple factors*:** The factors of place of service and applicable federal law are interrelated. However, federal law is weighted, because if there is a maternity/newborn admission claim, prior authorization cannot be required regardless of the place of service. As applied, both factors result in Aetna requiring precertification for inpatient admissions for M/S and MH/SUD benefits, except where federal law prohibits such a requirement.

(b) Determining services subject to precertification – Outpatient: factors for adding a service to the NPL

All M/S and MH/SUD services must meet one or more of the first three bulleted factors below to be added to the NPL (i.e., cost of treatment, high-cost growth, and/or variability in cost and practice). In addition, as explained below, a forecasted ROI of at least 3:1 is expected, but is not required, for an M/S or MH/SUD service to be added to the NPL. Finally, Aetna's NPL Committee may add a service to the NPL that doesn't meet these criteria if the Committee deems it appropriate based on the existence of certain extenuating factors. The below addresses all of these factors and how they are used in the application of precertification. Included in Step 5 is a table and explanation illustrating how each of the below factors was applied to those services that were added to the NPL in 2025.

- **Cost of treatment** is the measurement of the cost of an M/S or MH/SUD service.
  (a) ***How the factor is used to determine which benefits are subject to the NQTL***: As a general matter, an M/S or MH/SUD service may be added to the NPL if the average paid Medicare rate for a service is at least $150 based on Aetna's national paid Medicare claims experience. Cost of treatment is a factor reviewed by the NPL committee when deciding whether to add a service to the NPL. For both M/S and MH/SUD services, the NPL Committee completes a comprehensive review of each service proposed for addition to the NPL and updates the precertification list annually. The annual review is published in January each year. The Committee also performs a semi-annual review for any updates to the NPL in July. Committee members and business partners may submit items for precertification consideration throughout the year. During these reviews, the Committee considers the factors identified in Step 2, including the cost of treatment. The NPL Committee is comprised of clinicians and other subject matter experts who represent a broad range of Aetna programs. The senior Vice President of Clinical Services or designee will appoint a physician to chair the Committee. The Committee Chair approves voting members, which include

medical director representation from Aetna Student Health, Appeals, Behavioral Health, Government Programs, Individual/Public Exchange, State/Local Medical Management, Medical Policy, Commercial Clinical Specialty Operations, Aetna Clinical Solutions, Office of the Chief Medical Officer, and the Special Case Precert Unit.

The voting members collaborate and solicit input from key business partners to ensure delivery of a consistent guideline of high quality. Business partners include, but are not limited to, representation from, Medical Policy Operations (MPO) Coding, MPO Policy Solutions, Medicare, Business Compliance, Health Operations Policy Process, National and Regional Network, National Quality Management and Operation Leads. The Committee Chair considers and must approve the addition of members to represent other areas of the company. The NPL voting member roster is included in Appendix D. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standard that is relied upon when applying this factor is the average paid Medicare rate of at least $150, meaning that a service may be added to the NPL if its national average Medicare rate is at least that amount.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There is no deviation or variation from the factor of cost of treatment, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **High-cost growth** (projected or actual) is the measurement of material and sustained increase in the expenses associated with providing covered M/S and MH/SUD services.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: An M/S or MH/SUD service may be added to the NPL if, based on internal Aetna claims data, the per member per month expense for the services increased more than 10% in the most recent two-year period compared to an initial year baseline. High-cost growth is a factor reviewed by the NPL committee when deciding whether to add a service to the NPL. Please see the discussion above concerning the NPL Committee's composition and the structure of its deliberative process. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor:*** The evidentiary standard considered or relied upon in applying this factor is the growth in the per member per month expense for the services. If the expense for a service increases more than 10% in the most recent two-year period compared to an initial baseline, the service may be added to the NPL. For example, if the 2023 per member per month (PMPM)=$1.00, the 2024 PMPM=$2.00, and the 2025

PMPM=$3.00, then that would be a 200% trend increase over the two-year period. This is calculated by subtracting the 2023 PMPM from the 2025 PMPM and then dividing by the 2023 PMPM.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There is no deviation or variation from the factor of high-cost growth, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Variability in cost and practice** is the measurement of variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: An M/S or MH/SUD service may be added to the NPL if internal Aetna claims data demonstrates that there is greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period. Variability in cost and practice is a factor reviewed by the NPL committee when deciding whether to add a service to the NPL. Please see the discussion above concerning the NPL Committee's composition and the structure of its deliberative process. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor:*** The evidentiary standard considered or relied upon in applying this factor is internal Aetna claims data that demonstrates a greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment, in the most recent 12-month period. A service has a three-fold variability if the maximum value divided by the minimum value is greater than three. For example, if the cost per unit for a specific service within a 12-month period ranges between $100 and $350, the variability is 3.5 (3.5 = 350/100). Similarly, the variability in the range of the length of treatment and overall number of services per treatment are calculated the same way.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of variability in cost and practice, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Return on Investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: A forecasted ROI of at least 3:1 is expected for an M/S or MH/SUD service to be added to the NPL. A service may be added to the NPL if it does not have a forecasted ROI of at least 3:1 but one or more of the three criteria above (cost of treatment, high-cost growth, or variability in cost and practice) is met. Forecasted ROI is a factor reviewed by the NPL committee when deciding whether to add a service to the NPL. Please see the discussion above concerning the NPL Committee's composition and the structure of its deliberative process. This factor applies equally to M/S and MH/SUD services.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor:*** The evidentiary standard considered or relied upon in applying this factor is a forecasted ROI of at least 3:1. Forecasted ROI is produced by the review of expected claim experience and the estimated time needed for medical review to determine return on investment. There are two variables in the ROI calculation: (i) gross dollar amount of expected claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of estimated costs to administer precertification for that service. ROI is calculated by dividing (i) by (ii). The 3:1 ROI threshold has been utilized by Aetna for many years as part of its assessment of whether potential cost-containment initiatives warrant implementation and are deemed appropriate for purposes of adding, retaining or removing services, drugs and devices on the NPL.
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.
    (d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of return on investment, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- The following extenuating factors may also be considered for adding a service to the NPL: **patient safety**; **clinical quality control**; **marked variation in provider utilization patterns**; **incorrect utilization**; **application of CPBs; standards of industry practice.**
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: Extenuating factors are qualitative or quantitative points that, based on the expertise of Aetna's NPL Committee, warrant consideration in connection with adding, retaining or removing an M/S or MH/SUD service, drug or device from the NPL. Extenuating factors may be reviewed by the NPL Committee when deciding whether to add a service to the NPL. Any extenuating factors relied upon by the NPL

Committee must be documented. Please see the discussion above concerning the NPL Committee's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Extenuating factors:

- Patient safety – The evidentiary standards considered or relied upon in applying this factor are evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
- Clinical quality control – The evidentiary standards considered or relied upon in applying this factor are evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
- Marked variation in provider utilization patterns – The evidentiary standards considered or relied upon in applying this factor are the review of trends in provider utilization patterns and procedure codes for services that providers furnish, and how those trends align with clinical guidelines.
- Incorrect utilization – The evidentiary standards considered or relied upon in applying this factor are evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
- Application of CPB requirements – The evidentiary standards considered or relied upon in applying this factor are the large number of analyses and conclusions contained within the CPBs.
- Standards of industry practice – The evidentiary standards considered or relied upon for this factor are publicly available information and competitor analysis to determine whether precertification is appropriate for a given service at a given time (e.g., during a public health emergency).

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the extenuating factors, as they apply in the same way to MH/SUD and M/S benefits. However, there are times when a service may meet the criteria for inclusion on the NPL, but the NPL Committee exercises its business judgment not to add or retain it. Criteria the Committee may consider in exercising its judgment include the extenuating factors listed above, as well as burden on providers or members, delays or burdens in accessing timely care, expectations of members, plan sponsors and/or providers, and standards of industry practice. The NPL Committee must apply the same kinds of business judgment considerations, with the same degree of weight, to MH/SUD services as to M/S services. The specific business judgment considerations

in deciding not to include or retain a service on the NPL when it otherwise meets the criteria must be documented.

Relationship, ordering, and weighting of multiple factors: For both M/S and MH/SUD services, to be added to the NPL, a service must meet one or more of the factors of cost of treatment, high-cost growth and variability in cost and practice. In addition, a forecasted ROI of at least 3:1 is expected, but is not required, for a service to be added to the NPL. Lastly, the NPL Committee may add a service that does not meet the above criteria, based on the extenuating factors. There are no fixed quantitative standards for the extenuating factors; rather, they are evaluated in comparison to other services in the same benefit classification.

(c) Determining services subject to precertification – Outpatient: factors for retaining a service on the NPL

After the first year of being on the NPL, and annually thereafter, the ROI factor is calculated for all outpatient M/S and MH/SUD services on the NPL, and a decision is made by the NPL Committee to retain or remove a service from the NPL, as described below. Included in Appendix C is a table illustrating how the below factor was applied to those outpatient services that were retained on the NPL in 2025.

- **ROI** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: For both M/S and MH/SUD services, the NPL Committee completes one comprehensive review and updates the precertification list annually, which includes a review of the ROI factor, as described above. Please see the discussion above concerning the NPL Committee's composition and the structure of its deliberative process. For both M/S and MH/SUD services, if the actual ROI is 3:1 or greater, the service will be retained on the NPL. If the ROI is between 2:1 and 2.9:1, the NPL Committee will consider extenuating factors in deciding whether to retain a service. Finally, if the ROI ≤ 1.9:1 and not integral to NPL Group/Category (for example, breast reduction code may independently have a low ROI, but it is part of a procedure group for which precertification is required), the NPL Committee will consider the above-noted extenuating factors. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL:*** The evidentiary standard considered or relied upon in applying this factor is the actual ROI of at least 3:1. On an annual basis, Aetna's data analytics team extracts ROI data on each service/category on the NPL, and the NPL Committee reviews it as part of the annual retention review process. Actual ROI is produced by the review of actual claim experience and the actual resources needed for medical review. As

described above, there are two variables in the ROI calculation: (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service. ROI is calculated by dividing (i) by (ii). The 3:1 ROI threshold has been utilized by Aetna for many years as part of its assessment of whether potential cost-containment initiatives warrant implementation and are deemed appropriate for purposes of retaining or removing services, drugs, and devices on the NPL.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the ROI factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: For both M/S and MH/SUD services, while ROI is the primary factor in deciding whether to retain a service on the NPL, it is not an absolute determinant. The NPL Committee may also consider the factors used for adding a service to the NPL and/or any extenuating factors. There are no fixed quantitative standards for the extenuating factors; rather, they are evaluated in comparison to other services in the same benefit classification. The factors relied upon by the NPL Committee in making its determination must be documented.

(d) Factors for the process of precertifying services (inpatient and outpatient services)

For M/S and MH/SUD inpatient benefits, and those benefits in the outpatient–all other classification for which precertification is required, the below discussion addresses the factors used in the process of precertifying services.

- **National Committee for Quality Assurance (NCQA) Accreditation Standards -** NCQA sets utilization management standards for Health Plan accreditation and Managed Behavioral Health Organization accreditation.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna uses NCQA Health Plan and Managed Behavioral Health Organization Utilization Management Standards and Guidelines to adopt policies and procedures for the process of precertifying inpatient and outpatient M/S and MH/SUD services. These policies are outlined in Step 4, Part 2.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: NCQA Standards and Guidelines require timeliness standards for precertifying services on the NPL. Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy & Procedure establishes the timeliness

standards for urgent and non-urgent precertification requests that apply equally to M/S and MH/SUD services subject to precertification. These standards are outlined in Step 4, Part 2, and are contained in Attachment A of NCS 504. These standards are compliant with NCQA accreditation requirements for precertification, concurrent review, and retrospective review. Additionally, the NCQA Standards and Guidelines include requirements pertaining to the clinical criteria used in decision making, the review of relevant medical records, and the involvement of appropriate personnel in decision making. These requirements are implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure and are discussed in detail in Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in Aetna clinical policies.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to determine whether to authorize coverage for M/S and MH/SUD preauthorization requests.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon are the following guidelines utilized by Aetna's clinical staff during the precertification determination process:

- Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
- MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
- National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

- Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to determine whether to authorize coverage for M/S and MH/SUD precertification requests. This necessarily involves individualized evaluations and determinations for each member and request for coverage. Please see Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis for additional detail. Additionally, information regarding the nature and timing of the decisions, as well as the designations and qualifications of the clinical staff, is included herein in Step 4, Part 2. When making precertification decisions for M/S services, Aetna's clinical staff rely, as applicable to the particular service that is the subject of the precertification request, on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and/or applicable Aetna M/S Clinical Policy Bulletins. Similarly, when making precertification decisions for MH/SUD services, Aetna's clinical staff rely, as applicable to the particular service that is the subject of the precertification request, on American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Aetna's Applied Behavioral Analysis Medical Necessity Guide, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), and/or the appropriate Aetna MH/SUD Clinical Policy Bulletins. Staff are required to document the specific clinical guidelines relied upon when making benefit determinations within their documentation notes.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of generally accepted standards of medical practice and clinical appropriateness, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Applicable state and federal law** are regulatory requirements related to the timeframes, use of specific medical necessity criteria, and other requirements applicable to precertification.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna complies with applicable state and federal required timeframes for precertifying services. Aetna's NCS 504 Policy establishes national standard timeframes which comply with time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations. Aetna's NCS 503 Policy sets forth the medical necessity criteria used in reviewing precertification requests. State law or regulation that mandates a more stringent response time, use of specific medical necessity criteria, or other requirements applicable to precertification, supersedes Aetna's national standards.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon are timeframes, specific medical necessity criteria, or other standards that comply with applicable state and federal requirements for precertification requests. These standards are reflected in NCS 504 and NCS 503, and the state specific amendments to NCS 504 and NCS 503.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of applicable state and federal law, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering and weighting of multiple factors: The factors listed above apply to distinct aspects of the process of performing precertification**,** including decision-making and the timeliness and medical necessity standards applicable thereto. The factors are interrelated, and all operate together to ensure that Aetna employs an appropriate and effective precertification process. Aetna's national standards discussed above and set forth in NCS policies and procedures are based upon NCQA accreditation requirements and generally accepted standards of medical practice and clinical appropriateness. However, applicable law is weighted more heavily, as applicable law or regulation that mandates a more stringent response time, use of specific medical necessity criteria, or other requirements applicable to precertification, supersedes Aetna's national standards for applicable plans.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, for in-network benefits, Aetna conducts precertification for inpatient admissions and select ambulatory procedures and services. Accordingly, precertification applies to the following in-network benefit classifications: 1) inpatient and 2) outpatient–all other. As noted in Step 2, Part 1, two factors were used in the context of designing precertification: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Promotion of cost management and clinically appropriate utilization are general design factors and are the basis and rationale underlying Aetna's policies related to precertification requirements. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, both factors apply equally to both benefit types.

These general design factors are evidenced through general acknowledgement of cost management as a factor in CVS Health public filings noted in Step 3, Part 1, and the specific clinical guidelines identified in Step 2, Part 1, that reflect the clinically appropriate guidelines for both M/S and MH/SUD services. Additionally, Aetna's **UM Program Description** provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." While these materials refer to the general design factors of promotion of cost management and clinically appropriate utilization, there is no

written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of precertification with respect to M/S and MH/SUD benefits.

These factors apply equally to both benefit types and are not applied incomparably, or more stringently, to MH/SUD benefits in either the inpatient or outpatient–all other benefit classifications. Similarly, there are no deviations or variations from these two factors as they apply to the design of precertification. Aetna's analysis shows that as written, the processes, strategies, evidentiary standards or other factors used in designing precertification with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing precertification with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, for in-network benefits, precertification applies to the following benefit classifications: 1) inpatient and 2) outpatient–all other. As noted in Step 2, Part 2, different factors are applied in the context of precertification for: (a) determining services subject to precertification- inpatient; (b) determining services subject to precertification- outpatient: adding a service to the National Precertification List (NPL); (c) determining services subject to precertification- outpatient: retaining a service on the NPL; and (d) for those services for which precertification is required, the process for precertifying services. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying precertification to M/S benefits.

(a) Determining services subject to precertification – Inpatient

As set forth in Step 2, Part 2, the factors used in the application of precertification, to determine in-network inpatient services subject to precertification, are 1) place of service and 2) federal law. As written, for both M/S and MH/SUD, precertification applies to all inpatient admissions except for the limited instances noted herein: hospice care and maternity claims/newborn admissions within the standard length of stay. Aetna's analysis of applicable written materials demonstrates that the processes, strategies, evidentiary standards or other factors used to apply precertification to inpatient MH/SUD benefits are comparable to, and no more stringently applied than, those used to apply precertification to M/S benefits.

Per Aetna's **NCS 100: Precertification Policy** and its **Provider Manual**, precertification applies to inpatient admissions. The NPL memorializes Aetna's determination that all in-network inpatient admissions, whether M/S or MH/SUD, require precertification except for hospice and maternity and newborn stays that are within the standard length of stay. Aetna uses the factors 1) place of service and 2) applicable law, which are applied comparably to support the written policies which establish that all inpatient services, except for the exceptions noted, are subject to precertification. The place of service for a particular service is determined based on guidance of the National Uniform Billing Committee, which is the governing body for forms and codes used in facility bills. This guidance is used for both M/S and MH/SUD to establish inpatient status such that precertification is required. Aetna applies any applicable law in determining which services are/are not subject to precertification, which in this instance includes the federal Newborns' and Mothers' Health Protection Act of 1996 ("NMHPA"). Pursuant to the NMHPA, the health plan must automatically provide benefits for a hospital stay following delivery without requiring precertification. For stays that extend beyond the 48/96-hour minimum stay, authorization is required.

The factors of place of service and federal law are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of precertification to inpatient benefits. Regardless of whether the inpatient admission is for an M/S or MH/SUD condition, unless the admission cannot be subject to precertification due to federal law (NMHPA), or the admission is a hospice admission (which would apply whether the hospice admission is for an M/S or an MH/SUD condition), precertification is required. Both considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material used to apply precertification and determine which inpatient benefits are subject to precertification shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(b) Determining services subject to precertification – Outpatient: adding a service to the NPL

As noted in Step 2, Part 2, all services must meet one or more of the following criteria to be added to the NPL: cost of treatment, high-cost growth, and/or variability in cost and practice. Each of these factors is reflected in the **NPL Policy and Procedure,** which applies, as written, equally to M/S and MH/SUD services. In addition, a forecasted ROI of at least 3:1 is expected. This factor also applies, as written in the NPL Policy and Procedure, equally to M/S and MH/SUD services. Finally, if a service doesn't meet any of the above criteria, the NPL Policy and Procedure outlines the extenuating factors that could be considered by the NPL Committee. Those extenuating factors are: patient safety, clinical quality control, marked variation in provider utilization patterns, incorrect utilization, application of CPBs, and standards of industry practice.

Again, as written, those extenuating factors apply equally to M/S and MH/SUD services. Importantly, Aetna maintains one NPL Policy and Procedure which applies equally to M/S and MH/SUD benefits in deciding which services to add to the NPL.

Pursuant to the NPL Policy and Procedure, the NPL Committee evaluates these factors when considering proposed additions to the NPL. Such proposals can come from various sources, including NPL Committee members, product development, plan filings, and CMS coding changes. All submitters are required to provide a written rationale for presenting to the NPL Committee and provide a detailed description of the request including all applicable procedure and ICD diagnosis codes and descriptions and identified impacts to CPBs, product type, funding types, and place of service. To add a new service, drug, or device to the NPL, the submitter must identify which of the above factors apply, using an intake form which applies equally to M/S and MH/SUD services. The submission must include an impact analysis, including impacts to claims, appeals, and financial impacts related to claims from participating and non-participating providers. The submitter is responsible for consulting with applicable analysts and/or data scientists for the claim/call, financial, and appeals calculations and information, as these are components of the ROI that is expected to add a service to the NPL.

The NPL Committee considers the factors in Step 2, Part 2, and decides whether to add the service. As written in the NPL Policy and Procedure, there may be services that meet criteria for inclusion on the NPL, but the NPL Committee may exercise business judgment and determine not to add the service. Criteria the NPL Committee may consider in exercising its judgment are the extenuating factors listed in Step 2, Part 2, as well as burden on providers or members, delays or burdens in accessing timely care, expectations of members, plan sponsors and/or providers, and standards of industry practice. The NPL Committee must apply the same kinds of business judgment considerations, with the same degree of weight, to MH/SUD services as to M/S services. The specific business judgment considerations in deciding not to add a proposed service, drug or device to the NPL when it otherwise meets the criteria must be documented.

The factors discussed herein are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of precertification to MH/SUD outpatient–all other benefits. The same considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Notably, in 2025, one M/S service was considered for addition and was added to the NPL, while no MH/SUD services were considered for addition or added to the NPL. Accordingly, Aetna's analysis of the "as written" material (i.e., the NPL Policy and Procedure) used to apply precertification and determine the list of outpatient benefits subject to precertification by being added to the NPL shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services than to M/S services.

(c) Determining services subject to precertification – Outpatient: retaining a service on the NPL

The factor of ROI and its associated evidentiary standard and sources identified in Step 2, Part 2, are identified in the **NPL Policy and Procedure** as the primary factor for retaining M/S and MH/SUD services on the NPL. The factor of ROI, as written, applies equally to M/S and MH/SUD services. Also, per the written policy, the same underlying evidentiary standard and sources (i.e., 3:1 ROI using internal claims and administrative cost data) are applied to M/S and MH/SUD services.

While ROI is the primary factor in deciding whether to retain a service on the NPL, it is not an absolute determinant. The NPL Committee may also consider the factors for adding a service to the NPL and/or any extenuating factors. Again, as written, these factors and evidentiary standards and sources apply equally, as written, to M/S and MH/SUD services. The NPL Committee annually reviews services on the NPL to decide whether to retain or remove them. Any factors and extenuating factors relied upon in making the decision must be documented; this allows for validation that they are being applied comparably, and not more stringently, to MH/SUD services. A demonstration of how the NPL Committee conducted the 2025 annual NPL retention review and applied the factors listed in the NPL Policy to M/S and MH/SUD services in operation, is outlined in Step 5 below.

The NPL Policy and Procedure and factors discussed herein are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of precertification to MH/SUD outpatient–all other benefits. The same considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material (i.e., the NPL Policy and Procedure) used to apply precertification and determine the outpatient benefits subject to precertification by being retained on the NPL shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(d) The process of precertifying services (inpatient and outpatient)

As set forth above in Step 2, Part 2, the factors used in application, for the process of precertifying services (inpatient and outpatient) are: 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law. These factors support Aetna's written processes for precertifying services that are on the NPL. These processes are described in detail in the Aetna National Clinical Services (NCS) Utilization Management policies and procedures pertaining to precertification. Aetna maintains one set of written UM precertification policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to precertify in-network M/S and MH/SUD services:

- NCS 100: Precertification Policy & Procedure
- NCS 503: Medical Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure – VA amendment
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy – VA amendment
- NCS 505: Denial of Coverage Policy and Notification
- NCS 505: Denial of Coverage Policy and Notification – VA amendment
- NCS 506: Peer-to-Peer Review Policy
- NCS 506: Peer-to-Peer Review Policy – VA amendment
- NCS 510: Internal Quality Review Policy

Each of these policies is discussed in turn below, demonstrating that they support the factors outlined above and are comparably applied, as written, to M/S and MH/SUD services.

NCS 100 defines precertification and establishes the rules and processes for applying clinical criteria/guidelines to covered benefits for eligible members during the pre-service review process. As noted in the scope of the policy, this applies to M/S (called precertification) and MH/SUD (called behavioral health). Precertification includes confirming the member's eligibility, assessing medical necessity, pre-service discharge planning, determination of coverage and communication of coverage decisions to treating practitioners and members, and documentation of determinations to support accurate and timely claims adjudication.

The procedure section of NCS 100 details how precertification requests are administered. In brief, for M/S and MH/SUD services, precertification requests and supporting documentation are reviewed to verify member eligibility, the provider's network participation status, and the availability of benefits. Clinical support staff can issue administrative denials (due to member's lack of eligibility or benefit plan exclusions, for example). Coverage decisions that require clinical review are performed by licensed clinicians (e.g., Registered Nurse (RN), licensed clinical social worker (LCSW), licensed behavior analyst (LBA), licensed professional counselor (LPC)). The clinical precertification review follows the review procedure detailed in NCS 503, which is listed as a related material in the NCS 100 policy. The "as written" processes in NCS 100 used to review precertification requests are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. While NCS 100 refers to separate UM units that handle M/S and MH/SUD requests, the processes followed by those units are comparable and no more stringently applied to MH/SUD.

NCS 503 establishes the process of medical review and establish the written clinical criteria/guidelines used by Aetna's clinicians in making medical necessity determinations. This policy applies equally to M/S and MH/SUD services. For both M/S and MH/SUD services, the guiding strategy behind precertification relies upon the clinical reviewers' exercise of their clinical judgment, guided by clinical criteria, to determine whether to authorize coverage for

precertification requests. While NCS 503 sets forth separate written guidelines that apply to M/S and MH/SUD services, all services are subject to appropriate guidelines based on industry standards and generally accepted standards of medical practice and clinical appropriateness. NCS 503 otherwise does not differentiate between M/S and MH/SUD services. The relevant specific written guidelines referred to in NCS 503 are:

- **LOCUS and CALOCUS/CASII** (MH/SUD) – Aetna uses the most current versions of LOCUS and CALOCUS/CASII, which are recognized nationally as a generally accepted standard of care tool, to guide clinicians in making medically necessary level of care determinations for mental health services. The Level of Care Utilization System (LOCUS) assessment was developed by the American Association of Community Psychiatrists (AACP) in 1996 to help determine the mental health care resource intensity needs of adults. CALOCUS was developed was developed by the American Association of Community Psychiatrists in collaboration with the American Association of Child and Adolescent Psychiatry to help determine the mental health care resource intensity needs of children and adolescents.

- **ASAM** (MH/SUD) – Aetna uses the most current criteria published by the American Society of Addiction Medicine (ASAM) to guide clinicians in evaluating the medical necessity of levels and types of care for substance use disorders. ASAM Criteria are generally accepted, national standards for SUD treatment decisions and are recognized as such by many courts and regulators.

- **ABA Medical Necessity Guide** (MH/SUD) – Aetna's ABA medical necessity guidelines come from extensive review of the literature on the use of applied behavior analysis to treat autism spectrum disorder and a comparative review of the guidelines of other health insurers. A multidisciplinary committee of health care professionals within and external to Aetna Behavioral Health developed and approved the guidelines based on these reviews.

- **MCG Health Care Guidelines** (M/S) – Aetna uses the most current evidence-based Care Guidelines published by MCG Health to guide clinicians in making medically necessary level of care determinations for M/S services.

- **Aetna Clinical Policy Bulletins (CPBs)** (M/S and MH/SUD) – Aetna CPBs describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's medical necessity decisions regarding specific M/S and MH/SUD services.

- **NCCN Clinical Practice Guidelines in Oncology** (M/S) – Aetna uses the most current clinical practice guidelines published by the National Comprehensive Cancer Network (NCCN) to make medical necessity determinations in oncology clinical reviews. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are comprised of

recommendations for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines currently apply to more than 97% of cancers affecting patients in the United States. The NCCN Guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management.

- **Section 38.2-3418.17 of the Code of Virgina –** Aetna uses the VA specific legislation to establish procedures around handling prior-authorization requests for individuals receiving treatment for an autism spectrum disorder and prior authorization for drugs prescribed for the treatment of a mental disorder listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

Regarding application of state law, state amendments to NCS 503 reflect state law requirements applicable to precertification, including limitations on precertification requirements and/or the use of alternative M/S and MH/SUD medical necessity guidelines as required by state law where applicable. Medical necessity guidelines do not replace professional judgment exercised by properly trained, licensed, and experienced clinicians and professionals who evaluate the provision of services in accordance with accepted standards of care. As explained in NCS 503, individual M/S and MH/SUD medical necessity determinations are afforded independent clinical consideration based on the member's presentation. As listed in NCS 503, staff considers the individual needs of the member when utilizing guidelines, including, but not limited to age, co-morbidities, complications, progress of treatment, need for skilled care, psychosocial situation, risk related to ethnicity or genetic factors and home environment, when applicable. Staff additionally considers the following characteristics of the local health care delivery system during the coverage determination process: the ability of the provider to meet the member's cultural and language needs, as appropriate; the availability of highly specialized services, such as detoxification facilities; the availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and, the ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition. NCS 503 further notes that approval decisions may be automated when appropriate. Automation uses clinical information submitted by the provider and compares it to Aetna's clinical policies to render an approval decision, based on individualized clinical considerations, using the medical necessity guidelines outlined in NCS 503. For both M/S and MH/SUD medical necessity reviews, all adverse decisions are made by medical directors, never by automation or clinical staff who are not medical directors, as required by NCS 505: National Clinical Services Denial of Coverage Policy, discussed below. Thus, the "as written" material contained in NCS 503 pertaining to the medical review process is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 504 establishes the timeliness standards for urgent and non-urgent precertification determinations and notifications that apply equally to M/S and MH/SUD services. Attachment A to NCS 504 sets out timeliness standards for precertification decisions and notifications, separated into urgent precertification and non-urgent precertification requests. These timeliness standards apply equally to M/S and MH/SUD inpatient and outpatient precertification.

Urgent precertification requests

All MH/SUD inpatient admissions, including residential treatment center admissions, are considered urgent and follow the precertification determination timelines for urgent care in accordance with the instructions contained in NCS 504 and the VA amendment to NCS 504 for urgent precertification requests. For commercial plans, Aetna follows the DOL/ERISA claims regulation definition of urgent care. Urgent care is defined by this regulation as any request for medical care or treatment to which the application of the time periods for making non-urgent care decisions:

- Could seriously jeopardize the life or health of the member or the member's ability to regain maximum function, based on a prudent layperson's judgment; or,
- In the opinion of a practitioner with knowledge of the member's medical condition, would subject the member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request; or,
- In the opinion of a practitioner with knowledge of the member's medical condition, the request is urgent.

Per NCS 504, initial determinations for urgent precertification requests are made within 72 hours of the request. If additional information is required to make a determination, Aetna will initiate the request for additional information within 24 hours of the receipt of the request. Aetna will notify requester of the determination (approval or denial) verbally within 72 hours of the receipt of the request. For approvals, a written notification will be sent upon request. For denials, if direct telephonic notification is provided within 72 hours from the receipt of the request, then the written notification must be sent within 3 calendar days of the telephonic notice. These timelines apply equally to M/S and MH/SUD services. The information above applies except where modified by the Virginia Amendment. Refer to the Virginia Amendment for Virginia-specific requirements and provisions.

Non-urgent precertification requests

A non-urgent precertification request is one that does not meet the definition of urgent. Examples of M/S non-urgent requests include elective surgeries, such as a hysterectomy or bariatric surgery, or an electric wheelchair to replace a manual wheelchair. MH/SUD non-urgent requests are partial hospitalization, applied behavior analysis, and transcranial magnetic stimulation when they do not otherwise meet the urgent definition. Per NCS 504, initial determinations for non-urgent precertification requests are made within 15 calendar days of the request. If additional information is required to make a determination, Aetna will initiate the request for additional information within 15 calendar days of the receipt of the request. A verbal

and/or written determination is issued within 15 calendar days of the receipt of all necessary clinical information.

Additionally, **NCS 505** defines and outline the handling of denial of coverage determinations, including the responsibility for issuing clinical and administrative denial decisions, documentation requirements for denial decisions, and notification requirements for these coverage decisions. As written, this policy applies equally to M/S and MH/SUD services, which specifies that only M/S and MH/SUD medical directors can deny clinical coverage decisions. Because the processes are the same, the "as written" material contained in NCS 505 pertaining to the handling of coverage determination denials is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 506 outlines the peer-to-peer review process through which a treating practitioner, a clinician on behalf of the treating practitioner (e.g., genetic counselor for BRCA precertification requests) or a physician on behalf of a facility (for precertification denials) may request a discussion with a peer reviewer (licensed health plan physician medical director) or behavioral health consultant psychiatrist/psychologist/board certified behavior analyst-doctoral (BCBA-D), to discuss a clinical denial of coverage determination. Peer-to-peer is not an additional level of review or an appeal. It is a focused discussion between the provider representative and the peer reviewer. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D considers all available information when conducting a peer-to-peer review. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D reviews the applicable clinical criteria/guidelines in NCS 503, the clinical information that is present before and during the peer-to-peer discussion and uses clinical judgment to make a decision. For M/S, peer-to-peer reviews are conducted after a denial determination, upon request. For MH/SUD services, when clinically appropriate, peer-to-peer reviews are offered and conducted prior to the issuance of the initial coverage determination, in addition to peer-to-peer reviews that are available after a denial determination. As written, the process for peer-to-peer review is largely the same for M/S and MH/SUD, except that for MH/SUD services, Aetna may offer a peer-to-peer review before a determination has been issued, in addition to the peer-to-peer review that is available post-determination. Based upon the foregoing, the written material contained in NCS 506 pertaining to peer-to-peer review is comparably applied to MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

Finally, **NCS 510** describes Aetna's Internal Quality Review and Inter-Rater Reliability assessments. As written, the IQR/IRR process provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. Through inter-rater reliability (IRR) assessments, both M/S and MH/SUD medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria, and corrective actions are taken if the results do not meet certain metrics, which are the same for MH/SUD and M/S services. NCS 510 applies equally to M/S and MH/SUD services, and the processes set forth therein are the same for M/S

and MH/SUD services. The "as written" processes in NCS 510, for evaluation of medical director and utilization management clinician accuracy and consistency, are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. The IRR results for both Behavioral Health and Medical clinicians are discussed in Step 5, and show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

The factors of 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently, as written, to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the process of performing precertification. The written policies discussed above are equally applicable to performing precertification for M/S and MH/SUD inpatient and outpatient–all other services. The factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material used to perform precertification shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services than to M/S services.

Aetna provides members with appeal rights when an adverse benefit determination is issued. When Aetna issues a denial of services or a reduction in coverage due to an EIU determination or blanket exclusion, that determination is considered an adverse benefit determination. Members have the right to request a review of that determination through the appeal process and may initiate an appeal by contacting Aetna.

Appeal rights and procedures are described in the COC under the section titled "Appeal of an Adverse Benefit Determination." The COC outlines the appeal process, including applicable timeframes, who may request an appeal on behalf of the member, how appeals are assigned and reviewed, and the options available if the member is not satisfied with the appeal decision. Aetna does not maintain separate appeal processes for MH/SUD services and M/S services; the same appeal procedures apply to both. In addition, once the internal appeal process has been exhausted, members may have the right to request an external review, as described in the COC. The COC also explains the circumstances under which external review may be available and the procedures for requesting it. The appeal and external review rights available to members are applied consistently for MH/SUD and M/S services and are not more stringent for MH/SUD services than for M/S services.

Summary

In sum, Aetna's analysis demonstrates that as written, the processes, strategies, evidentiary standards, and other factors used in applying precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying precertification to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

** The quantitative data presented in this analysis is based on Aetna Life Insurance Company (ALIC) business, which represents approximately 74% of the total Virginia business. The NQTL processes, strategies, evidentiary standards, and other factors described herein are applied consistently across the relevant Virginia business. As a result, Aetna believes the ALIC data is representative of the operational application of the NQTL and provides a reliable basis for assessing compliance with MHPAEA's comparative analysis requirements and for supporting the findings and conclusions presented in this report.*

As noted in Step 1, for in-network benefits, precertification applies to the following benefit classifications: 1) inpatient and 2) outpatient–all other. As noted in Step 2, Part 2, different factors are applied in the context of precertification for: (a) determining services subject to precertification- inpatient; (b) determining services subject to precertification- outpatient: adding a service to the NPL; (c) determining services subject to precertification- outpatient: retaining a service on the NPL; and (d) for those services for which precertification is required, the process for precertifying services. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying precertification to M/S benefits.

(a) Determining services subject to precertification – Inpatient

In operation, precertification is required for inpatient admissions for both M/S and MH/SUD services except as noted above with respect to inpatient maternity and hospice, which

are equally applicable to M/S and MH/SUD conditions. Thus, in operation, the processes, strategies, evidentiary standards and factors used to determine which MH/SUD inpatient services are subject to precertification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and factors with respect to M/S services.

(b) Determining services subject to precertification – Outpatient: adding a service to the NPL

As noted previously in this analysis, the NPL Committee considers the above-listed factors, evidentiary standards, and sources when determining whether to add a new service to the NPL. As also noted previously, those factors, evidentiary standards and sources are applied equally, and thus comparably, to M/S and MH/SUD services. A review and comparison of the list and number of services that require precertification, for M/S and MH/SUD, further provides a basis to evaluate whether, in operation, the factors, evidentiary standards, and sources for determining services subject to precertification are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits.

In calendar year 2025, there were:

- Zero (0) MH/SUD services considered for addition or added to the NPL, and
- One (1) M/S service considered, and added, to the NPL.

For outpatient–all other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 29 procedure groups of M/S services. As stated above, in 2025, no MH/SUD services were added to the NPL. Further, **no** new MH/SUD services have been added to the NPL in the past 7 years, since the framework for inclusion/retention was finalized. This demonstrates that, in practice and operation, Aetna has determined to add fewer (as in, zero) MH/SUD services to the list of services requiring precertification than M/S services. Thus, in operation, the processes, strategies, evidentiary standards, and factors used to determine whether to add new MH/SUD services to the NPL are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and factors with respect to M/S services.

(c) Determining services subject to precertification – Outpatient: retaining a service on the NPL

As noted previously, the NPL Committee annually reviews services on the NPL to decide whether to retain or remove them. As also noted previously, any factors and extenuating factors relied upon in making the decision must be documented, as this allows for validation that the NPL Committee is applying those factors comparably, and not more stringently, to MH/SUD services. A review and comparison of this analysis for M/S and MH/SUD provides a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for determining services

subject to precertification are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits.

In the NPL Committee's 2025 annual retention review, which is based upon 2024 book of business data, all M/S and MH/SUD services that demonstrated an ROI calculation of at least 3:1 were retained on the NPL. Regarding MH/SUD services, all MH/SUD services on the NPL demonstrated an ROI of 3:1 and thus were retained on the NPL. Accordingly, the NPL Committee did not rely upon any of the extenuating factors with respect to MH/SUD services retained on the NPL. Regarding M/S services, there were seven M/S services that did not demonstrate an ROI calculation of 3:1, and were reviewed by the NPL Committee for possible retention based on the extenuating factors. All services but one were retained on the NPL. Below are tables listing all services identified in the NPL Committee's 2025 annual retention review that did not demonstrate an ROI calculation of at least 3:1, and the NPL's application of extenuating factors and decision whether or not to retain the service on the NPL:

NPL Committee 2025 Annual Retention Review

MH/SUD services: None. All MH/SUD services on the NPL demonstrated an ROI calculation of at least 3:1, based upon the NPL Committee 2025 Annual Retention Review.

NPL Category	Procedure Group	Net ROI	Application of Extenuating Factor	Result
None	N/A	N/A	N/A	N/A

M/S Services: The following M/S services did not demonstrate an ROI calculation of at least 3:1, based upon the NPL Committee 2025 Annual Retention Review.

NPL Category	Procedure Group	Net ROI	Application of Extenuating Factor	Result
DME	Electric Scooter	Less than 3:1	No	Approved for removal from NPL
Transplants	Multivisceral Organs	Less than 3:1	Yes; Clinical quality control	Retained on NPL
Transplants	Heart/Lung Transplant	Less than 3:1	Yes; Clinical quality control	Retained on NPL
Transplants	Heart	Less than 3:1	Yes; Clinical quality control	Retained on NPL
Transplants	Pancreas Transplant	Less than 3:1	Yes; Clinical quality control	Retained on NPL
Other Services	Dialysis	Less than 3:1	Yes; Incorrect utilization	Retained on NPL
Women's Health and Infertility	BRCA Genetic Testing	Less than 3:1	Yes; Marked variation in provider utilization patterns	Retained on NPL

These results are based on book of business data. The data shows that seven M/S services and zero MH/SUD services had ROI calculations that fell below the 3:1 threshold. The NPL Committee further evaluated the M/S services that did not demonstrate a 3:1 ROI. Based on this, the NPL Committee clearly applied, in operation, the afore-referenced factors to MH/SUD services in a manner that was comparable to and no more stringent than how the Committee applied them to M/S services.

(d) The process of precertifying services (inpatient and outpatient)

Aetna monitors the denial rates for M/S and MH/SUD precertification requests as one measure that can evaluate whether precertification is applied comparably, and not more stringently, to MH/SUD services compared to M/S services. Evaluation of this data for M/S and MH/SUD services can provide a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the precertification process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits.

The data below reflects the in-network precertification decisions for inpatient services and outpatient services on the NPL, for Virginia's insured book of business from 06/30/2025-07/01/2026. This data is retrieved from Aetna's utilization management system. The data reflects the total number of decisions and the total number of decisions that were denied, and is further broken down into administrative denials and medical necessity denials. The data is separated into the inpatient and outpatient–all other benefit classifications. Administrative denials are based on failure to meet plan administrative requirements, including the member's lack of eligibility, missing information required to complete the review, the benefits for the requested services are excluded under the member's plan, or the benefits have been exhausted under the member's plan. Medical necessity denials are denials for which the requested service did not meet the medical necessary criteria used by clinicians during the precertification process.

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Denial Rates for In-Network Precertification Requests

Denial Rates for In-Network Precertification Requests
7/1/25-6/30/26

In-Network Precertification Decisions	Inpatient M/S	Inpatient MH/SUD	Outpatient All Other M/S	Outpatient All Other MH/SUD
Total Decisions	444	6	714	51
Denied Decisions	100	0	208	12
Overall Percent Denied	**22.52%**	**0.0%**	**29.13%**	**23.53%**
Total Administrative Denials	38	0	52	0
Percent Denied - Administrative	**8.56%**	**0.0%**	**7.28%**	**0.0%**
Total Medical Necessity Denials	62	0	156	12
Percent Denied – Medical Necessity	**13.96%**	**0.0%**	**21.85%**	**23.53%**
Total Number of PA Medical Necessity Reviews **approved** from an **internal physician review**	91	0	164	4
Total Number of PA Medical Necessity Reviews **approved** from an internal **peer-to-peer review**	23	0	17	0
Total Number of PA Medical Necessity Reviews **denied** from an **internal physician review**	62	0	156	12
Total Number of PA Medical Necessity Reviews **denied** from an internal **peer-to-peer review**	7	0	38	3

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In-Network Precertification Decisions	**Inpatient M/S**	**Inpatient MH/SUD**	**Outpatient All Other M/S**	**Outpatient All Other MH/SUD**
Total Number of PA Medical Necessity Reviews from a **first level review resulting in lower-level care and partial denials**	0	0	0	0
Total Number of PA Medical Necessity Reviews from an **internal physician review resulting in lower-level care and partial denials**	0	0	0	0
Total Number of PA Medical Necessity Reviews from a **peer-to-peer review resulting in lower-level care and partial denials**	0	0	0	0
Total number of PA Medical Necessity Reviews from a **first level review escalated to an internal review**	153	0	320	16
Total number of PA Medical Necessity Reviews from an **internal physician review escalated to an internal review**	30	0	55	3
Total Number of PA Medical Necessity Reviews in **peer-to-peer review escalated to an internal review**	0	0	0	0

Inpatient

The overall precertification denial rate for inpatient MH/SUD services was lower than for M/S services (0% vs. 22.52%). Additionally, both the administrative denial rate and the medical necessity denial rate were lower for MH/SUD services, with no denials observed for MH/SUD claims compared to rates of 8.56% and 13.96%, respectively, for M/S claims. Accordingly, these results indicate that, in operation, precertification was applied at least comparably, and not more stringently, to MH/SUD services than to M/S services within the inpatient benefit classification.

Outpatient–All Other

Similarly, the overall precertification denial rate for outpatient MH/SUD services was lower than for M/S services (23.53% vs. 29.13%). In addition, the administrative denial rate was lower for MH/SUD services, with no administrative denials observed for MH/SUD claims compared to 7.28% for M/S claims. The medical necessity denial rate for MH/SUD services was modestly higher than for M/S services (23.53% vs. 21.85%). Overall, the data reflects that, in operation, precertification is applied at least comparably, and not more stringently, to MH/SUD services than to M/S services within the outpatient benefit classification.

Additionally, the IRR process described in NCS 510: Internal Quality Review Policy & Procedure provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. In that process, medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria. Corrective actions are taken if the results do not meet certain individual and business unit metrics, which are the same for M/S and MH/SUD. The IRR results for both Behavioral Health and Medical clinicians and medical directors show that the audits were performed as required and the overall goals met. Overall, the final score for M/S utilization reviews was 98%. For MH/SUD, the final score was 100%. These IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

In sum, review of the data addressed herein provides a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the precertification process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits. Based on the in-operation data and reviews discussed above, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying precertification with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying precertification with respect to M/S benefits in the applicable benefit classifications.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, precertification is a pre-service utilization review performed by licensed healthcare professionals to determine medical necessity and appropriateness of treatment for certain M/S and MH/SUD services. Precertification applies to M/S and MH/SUD inpatient benefits, and certain M/S and MH/SUD outpatient benefits listed on Aetna's NPL. As further demonstrated in Step 1, in-network precertification applies to the following benefit classifications: 1) in-network inpatient and 2) in-network outpatient–all other.

Step 2 identified the factors that are used to: 1) determine the inpatient services subject to precertification; 2) determine the outpatient services subject to precertification, pertaining to adding an outpatient service to the NPL; 3) determine the outpatient services subject to precertification, pertaining to retaining an outpatient service on the NPL; and 4) how to apply precertification to inpatient and outpatient services. Step 3 explained the evidentiary standards and sources for those factors and how they are used in the design and application of precertification. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD services. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD services subject to precertification and concluded that there are no written differences in that application that results in any MH/SUD services being treated more stringently than, or incomparably to, M/S services. Finally, Step 5 demonstrated that, in operation, inpatient and outpatient M/S and MH/SUD services are subject to precertification in a comparable manner. In the process of conducting precertification, the MH/SUD inpatient and outpatient services to which

precertification applies are treated substantively and administratively in a comparable and no more stringent manner than M/S services.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors, evidentiary standards, and sources to M/S and MH/SUD benefits in determining which services require precertification and in conducting precertification. Two factors are used in the context of designing precertification: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Promotion of cost management and clinically appropriate utilization are general design factors and are a basis and rationale underlying Aetna's policies related to precertification requirements. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits.

In the application of precertification, the factors used to determine inpatient services subject to precertification are 1) place of service and 2) federal law. Both in writing and in operation, precertification applies to all M/S and MH/SUD inpatient admissions except for the limited instances noted herein, which have no impact on this parity analysis. In the application of precertification with respect to outpatient services, Aetna maintains one NPL Policy and Procedure which applies equally to M/S and MH/SUD benefits in deciding which services to add to the NPL, and the decisions are made by the same NPL Committee which includes both M/S and MH/SUD representation.

As discussed above, all M/S and MH/SUD services must meet one or more of the following criteria to be added to the NPL: cost of treatment, high-cost growth and/or variability in cost and practice. In addition, a forecasted ROI of at least 3:1 is expected. Finally, if a service does not meet any of the above criteria, the NPL Policy and Procedure outlines the extenuating factors that may be considered by the NPL Committee. After the first year of being on the NPL, and annually thereafter, the ROI factor is calculated for all outpatient M/S and MH/SUD services on the NPL, and a decision is made by the NPL Committee to retain or remove a service from the NPL based upon that and, as applicable, the additional factors discussed above. Both in writing and in operation, the same factors, evidentiary standards and sources are used to determine the M/S and MH/SUD outpatient services that are added to and retained on the NPL and are subject to precertification. Finally, the factors used in application, for the process of precertifying services (inpatient and outpatient) are: 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law. These factors support Aetna's written processes for performing precertification. These processes are described in detail in the Aetna Utilization Management policies and procedures pertaining to precertification. Aetna maintains one set of written UM precertification policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to perform precertification for M/S and MH/SUD inpatient and outpatient services. The factors, and

the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD.

As demonstrated in Step 5, in operation, precertification is required in a comparable manner for inpatient admissions for both M/S and MH/SUD services. Regarding outpatient–all other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 29 procedure groups of M/S services. Similarly, an in-operation review of the services added to the NPL during 2025 shows that no new MH/SUD services were added to the NPL while one new M/S service was added to the NPL. During the review to determine whether to retain or remove services from the NPL as conducted by the NPL Committee in 2025, no services that demonstrated an ROI calculation of at least 3:1 were removed from the NPL. All of the 4 MH/SUD services on the NPL demonstrated an ROI of at least 3:1 and were retained accordingly. There were 7 M/S services that did not demonstrate an ROI calculation of 3:1. Of those services, based on the NPL's committee's review, 6 were maintained on the NPL and one was approved for removal from the NPL. From this information, Aetna may conclude that the factors, evidentiary standards, and sources used to determine which inpatient and outpatient services are subject to precertification are applied in a comparable, and not more stringent manner, for MH/SUD services.

As further demonstrated in Step 5, an in-operation review of in-network precertification determinations for the 2025 insured book of business indicates that, with respect to the precertification process, denial rates for MH/SUD services were lower than those for M/S services across both inpatient and outpatient-all other service categories. Specifically, for inpatient services, the overall precertification denial rate was 0.0% for MH/SUD services (0 denials out of 6 determinations), compared to 22.52% for M/S services (100 denials out of 444 determinations). For outpatient-all other services, the overall precertification denial rate was 23.53% for MH/SUD services (12 denials out of 51 determinations), compared to 29.13% for M/S services (208 denials out of 714 determinations). These results indicate that the precertification process does not operate more stringently for MH/SUD services than for comparable M/S services, as MH/SUD services experienced lower denial rates in both classifications.

Additionally, an in-operation review of the IRR results shows that both Medical and Behavioral Health medical directors and clinicians are performing utilization management reviews accurately and consistently overall. The final overall score for M/S utilization reviews was 98%. For MH/SUD, the final overall score was 100%.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes,

strategies, evidentiary standards, and other factors used in designing and applying precertification to M/S benefits across the applicable benefit classifications. The factors, evidentiary standards and sources used to determine what services are subject to precertification, and to actually conduct precertification, are designed and applied in a comparable, and not more stringent manner, for MH/SUD benefits in all applicable benefit classifications both in writing and in operation. Taken together with the favorable outcomes for MH/SUD at the book of business level, the precertification NQTL is designed and applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Behavioral Health Medical Director, Quality and Mental Health Parity, Medical Doctor board certified in Psychiatry • Lead Director, Clinical Review Program Management • Sr. Manager, Clinical Health Services, LCSW • Manager, Health Services, Clinical Review Program Management, RN, BSN

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Nonquantitative Treatment Limitation Comparative Analysis:

PRECERTIFICATION (aka PRIOR AUTHORIZATION) – OUT-OF-NETWORK

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of precertification,* ***(2)*** *an identification of all* ***out-of-network*** *mental health/substance use disorder (MH/SUD) and medical/surgical (M/S) benefits to which precertification applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: *Out-of-Network* Precertification [45 CFR 146.137(c)(1)(i)]

Precertification is a pre-service utilization review performed by licensed healthcare professionals to determine medical necessity and appropriateness of treatment for certain services (identified in Part 2 below). Ultimately, this review will inform whether those services are eligible for payment under the terms of the health benefit plan. Precertification applies to M/S and MH/SUD inpatient admissions and certain M/S and MH/SUD outpatient services. This is considered a clinical review form of prior authorization. Aetna does not conduct other forms of prior authorization. The following materials describe out-of-network precertification:

1. Plan Documents

Aetna's standard certificate of coverage provides:

Certificate of Coverage

Medical necessity [and precertification] requirements

Medical necessity and precertification requirements

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

[Precertification

You need pre-approval from us for some **covered services**. Pre-approval is also called **precertification**.

[Out-of-network

[When you go to an **out-of-network [provider]**, you are responsible to get any required **precertification** from us.] [When you go to a **[provider]**, you are responsible to get any required **precertification** from us.] If you don't **precertify**:

- Your benefits may be reduced, or the plan may not pay. See your schedule of benefits for details.
- You will be responsible for the unpaid bills.
- Your additional out-of-pocket expenses will not count toward your **deductible** or **maximum out-of-pocket limit**, if you have any.]

[Timeframes for **precertification** are listed below. For **emergency services**, **precertification** is not required, but you should notify us as shown.

To obtain **precertification**, contact us. You, your **[physician]** or the facility must call us within these timelines:

Type of care	Timeframe
Non-emergency admission	Call at least [14 days] before the date you are scheduled to be admitted
Emergency admission	Call within [48 hours] or as soon as reasonably possible after you have been admitted
Urgent admission	Call before you are scheduled to be admitted
Outpatient non-emergency medical services	Call at least [14 days] before the care is provided, or the treatment or procedure is scheduled

An urgent admission is a **hospital** admission by a **[physician]** due to the onset of or change in an illness, the diagnosis of an illness, or injury.

We will tell you and your **[physician]** in writing of the **precertification** decision, where required by state law. An approval is valid for [30-180 days] as long as you remain enrolled in the plan.

For an inpatient **stay** in a facility, we will tell you, your **[physician]** and the facility about your **precertified** length of **stay**. If your **[physician]** recommends that you stay longer, the extra days will need to be **precertified**. You, your **[physician]**, or the facility will need to call us as soon as reasonably possible, but no later than the final authorized day. We will tell you and your **[physician]** in writing of an approval or denial of the extra days.

If you or your **[provider]** request **precertification** and we don't approve coverage, we will tell you why and explain how you or your **[provider]** may request review of our decision. See the *Complaints, claim decisions [and appeal procedures]* section.]

Types of services that require precertification
Precertification is required for inpatient **stays** and certain outpatient services and supplies.
[Precertification is required for the following types of services and supplies:
[Inpatient –

- [Gender affirming treatment]
- [Gene-based, cellular and other innovative therapies (GCIT)]

- [Obesity (bariatric) **surgery]**
- **Stays** in a hospice facility
- **Stays** in a **hospital**
- **Stays** in a rehabilitation facility
- **Stays** in a **residential treatment facility** for treatment of **mental health disorders** and **substance related disorders**
- **Stays** in a **skilled nursing facility**]

[Outpatient –

- [Applied behavior analysis]
- [ART services]
- Complex imaging
- Cosmetic and reconstructive **surgery**
- [Gender affirming treatment]
- [Gene-based, cellular and other innovative therapies (GCIT)]
- [Home health care]
- Hospice care
- Injectables, (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications)
- Kidney dialysis
- Knee **surgery**
- [Limited infertility services]
- Non-emergency transportation by airplane
- [Obesity (bariatric) **surgery]**
- Outpatient back **surgery** not performed in a **[physician's]** office
- Partial hospitalization treatment – **mental health disorders** and **substance related disorders** treatment
- [Private duty nursing services]
- Sleep studies
- Transcranial magnetic stimulation (TMS)
- Wrist **surgery**]

Contact us to get a complete list of the services that require **precertification**. The list may change from time to time.]

Glossary Definition

Medically necessary, medical necessity

Medically necessary, medical necessity (mental health or substance use disorder)

A service or product addressing the specific needs of a patient for the purpose of screening, preventing, diagnosing, managing, or treating such disorder, including:

- Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care
- Clinically appropriate in terms of type, frequency, extent, site, and duration

- Not defined primarily for the economic benefit of an insurer or purchaser or for the convenience of the patient, treating physician, or other health care provider.

Generally accepted standards of mental health or substance use disorder care means evidence-based independent standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment. Sources reflecting "generally accepted standards of mental health or substance use disorder care" include:

- Peer-reviewed scientific studies and medical literature
- Consensus guidelines and recommendations of nonprofit health care provider professional associations and specialty societies
- Nationally recognized clinical practice guidelines, including:
  - Patient placement criteria
  - Service intensity assessment instruments
  - Clinical practice guidelines
  - Guidelines and recommendations of federal government agencies
  - Drug labeling approved by the U.S. Food and Drug Administration

Important note:
We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Medically necessary, medical necessity (other than mental health or substance use disorder)

Health care services or supplies that prevent, evaluate, diagnose or treat an illness, injury, disease or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with “generally accepted standards of medical practice”
- Clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease
- Not primarily for your convenience, the convenience of your **[physician]**, or other health care **[provider]**
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your illness, injury or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and
- Following the standards set forth in our clinical policies and applying clinical judgment

Important note:
We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Health care services or supplies that prevent, evaluate, diagnose, or treat an illness, injury, disease, or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with "generally accepted standards of medical practice"
- Clinically appropriate, in terms of type, frequency, extent, site, place of service, duration, and considered effective for your illness, injury or disease
- Not primarily for your convenience, the convenience of your **[physician]**, or other health care **[provider]**
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your illness, injury, or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and
- Following the standards set forth in our clinical policies and applying clinical judgment

Important note:
We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care- professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Precertification, precertify

Pre-approval that you or your **[provider]** receives from us before you receive certain **covered services**.

Schedule of Benefits

[Precertification covered services reduction

[This only applies to out-of-network **covered services**:]

Your certificate contains a complete description of the **precertification** process. You will find details in the [*How your plan works – Medical necessity [and precertification] requirements* section.

If **precertification** for **covered services** isn't completed, when required, it results in the following benefit reduction:

- [A [0%-50%] **coinsurance** reduction applied separately to the benefit provided for each **covered service**
- A benefit reduction of [0%-50%] up to a maximum of [$100-$500] for each type of **covered service**
- **Covered services** reduced by the lesser of [0%-50%] of the benefit that would have been payable and [$100-$500]
- A [$100-$500] benefit reduction applied separately to each type of **covered service**
- The service is not covered]

You may have to pay an additional portion of the **allowable amount** because you didn't get **precertification**. This portion is not a **covered service** and doesn't apply to your **deductible** or **maximum out-of-pocket limit**, if you have one.]

2. Policies and Procedures

The following internal policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address precertification:

- **Aetna Member Precertification List (MPL) P&P** – Aetna's policy for maintaining the standard list of services, drugs and devices that members are required to precertify for coverage as out-of-network benefits under Aetna's standard benefit plans. This is known as the Member Precertification List (MPL).
- **NCS 100: Precertification P&P** – Aetna policy defining precertification and providing the rules and processes for applying clinical criteria/guidelines to covered benefits for eligible members during the pre-service review process.
- **NCS 503: Medical Review P&P** – Aetna's policy that explains the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
    - **National Clinical Services (NCS) 503 Medical Review – Virginia**
        - This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
- **NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy** – Aetna's policy outlining the timeliness standards for notifying members/providers of coverage decisions.

    - **National Clinical Services (NCS) 504 Timeliness Standards for Coverage Decisions and Notification Policy - Virginia**
        - This amendment will be used in conjunction with NCS 504 to comply with Virginia requirements.
- **NCS 505: Denial of Coverage Policy and Notification** – Aetna's policy defining and outlining the handling of denial of coverage determinations.
    - **National Clinical Services NCS 505: Denial of Coverage Policy and Notification – Virginia**
        - This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements.
- **NCS 506: Peer-to-Peer Review Policy** – Aetna's policy that describes the process for treating practitioners/clinicians/physicians to discuss a clinical denial with a peer reviewer or behavioral health consultant/psychiatrist/psychologist.
    - **National Clinical Services NCS 506: Peer-to-Peer Review – Virginia**
        - This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.
- **NCS 510: Internal Quality Review Policy** – This policy describes the internal quality review process to assess the compliance with policies and procedures for individuals who support the health plan's medical management programs.

Additionally, Aetna's Care Management Program Description ("**UM Program Description**"), which applies to M/S and MH/SUD benefits, encompasses Aetna's utilization management program. The UM Program Description defines the scope, goals and objectives, processes, and monitoring of precertification and other utilization management programs. Aetna maintains a comprehensive vendor oversight program applicable to all third-party entities that perform functions related to the administration of covered benefits. Under this program, vendors are contractually required to operate in accordance with Aetna's policies, procedures, clinical guidelines, and oversight requirements, regardless of whether the services provided relate to benefits or MH/SUD benefits. Aetna utilizes Evicore to perform certain clinical administrative functions, including precertification and prior authorization review activities. Aetna approves vendor criteria through Utilization Management committees and clinical policy review. Our vendors services support the administration of both M/S and MH/SUD benefits, as applicable.

There are no separate vendor-specific prior authorization requirements, evidentiary standards, or decision-making frameworks used by our vendors for MH/SUD benefits versus M/S benefits. Prior authorization determinations conducted by our vendors are made in accordance with Aetna utilization management policies, clinical guidelines, and operational procedures applicable to the benefit being reviewed. Aetna retains responsibility for oversight of vendor performance and compliance with contractual obligations, regulatory requirements, and applicable Aetna standards. Through its ongoing governance and monitoring processes, Aetna evaluates vendor operations to ensure that utilization management activities, including prior

authorization reviews, are administered consistently with Aetna's policies and procedures for both MH/SUD and M/S benefits.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)], and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Overview

For out-of-network benefits, precertification applies to inpatient admissions and certain outpatient services and supplies. Precertification applies to the services listed in the member's certificate of coverage, referred to as the Member Precertification List (MPL). The MPL is part of the certificate of coverage. It describes which services (if any) are subject to precertification and what the consequences are (if any) of failing to obtain it. Members are responsible for seeking precertification of services on the MPL.

Benefits and Classification

Precertification applies to M/S and MH/SUD benefits in the following benefit classifications, as set forth below: **out-of-network inpatient**; **out-of-network outpatient**–**all other**.

Benefit Classifications to which NQTL Applies: ✔ **OON IP** ✔ **OON OP AO**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
OON Inpatient All inpatient admissions, including hospital, skilled nursing facilities, rehabilitation facilities, and hospice facilities, except maternity/newborn stays within the standard length of stay	**OON Inpatient** All inpatient admissions including residential treatment facilities
OON Outpatient – All Other • Advanced reproductive technology (ART) services • Complex imaging • Cosmetic and reconstructive surgery • Gene-based, cellular and other innovative therapies (GCIT) • Home health care • Hospice care	**OON Outpatient – All Other** • Applied behavioral analysis (ABA) • Gender affirming treatment • Partial hospitalization program (PHP) • Transcranial magnetic stimulation (TMS)

• Injectables (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications) • Kidney dialysis • Knee surgery • Limited infertility services • Non-emergency transportation by airplane • Obesity (bariatric) surgery • Outpatient back surgery not performed in a physician's office • Private duty nursing services • Sleep studies • Wrist surgery	

<u>Step 2</u>: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of precertification. Each subpart includes,* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to precertification, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL.

Factor	Applicable to M/S	Applicable to MH/SUD
Cost management	✓	✓
Clinically appropriate utilization	✓	✓

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

- **Clinically appropriate utilization** is a **factor** that seeks to ensure that M/S and MH/SUD treatments, procedures, or services are appropriate for the diagnosis, severity of illness, and overall health status of a patient, and that they are provided in accordance with evidence-based guidelines and practices that are relevant to the condition being treated and that avoids misuse of care.

- In accordance with Virginia's standard certificate of coverage, for M/S services to be medically necessary, they should be "In accordance with generally accepted standards of medical practice, clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease". Medical necessity is comparably described in the COC for MH/SUD services as "Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care and considered clinically appropriate in terms of type, frequency, extent, site, and duration." In general, the following sources contain the evidentiary standards (i.e., clinical treatment guidelines) that are used in the design of this NQTL to support the factor of clinically appropriate utilization. However, for insured plans in some states, applicable state law may require Aetna to apply an alternative standard:
    - MCG Health Care Guidelines
    - National Comprehensive Cancer Network Treatment guidelines
    - American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*
    - Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS)
    - Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII)
    - Aetna's Applied Behavioral Analysis Medical Necessity Guide
    - Aetna Clinical Policy Bulletins

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) determining services subject to precertification- inpatient, (b) determining services subject to precertification- outpatient: adding a service to the Member Precertification List (MPL), (c) determining services subject to precertification- outpatient: removing a service from the MPL, and (d) for those services for which precertification is required, the process for precertifying services (inpatient and outpatient).

(a) Factors for determining services subject to precertification – Inpatient

Factor	Applicable to M/S	Applicable to MH/SUD
Place of service	✓	✓
Federal law	✓	✓

- **Place of service** is a factor used to evaluate whether services are subject to a precertification requirement. Place of service refers to an inpatient admission to a hospital or other healthcare facility (e.g. skilled nursing facility, rehabilitation facility, or residential treatment facility), usually requiring an overnight stay and including room, board, and general nursing care. The **evidentiary standards and sources** upon which this factor is based are:
  - All inpatient admissions, except maternity/newborn admissions within the standard length of stay are subject to precertification.
  - Place of service is determined based on the bill classification identified on the facility claim submission.

- **Federal law** consists of regulatory and legal requirements concerning precertification requirements for inpatient services. The **evidentiary standards and sources** upon which this factor is based are:
  - Applicable federal laws and regulations, specifically, the federal Newborns' and Mothers' Health Protection Act (NMHPA) of 1996 which sets minimum length of stay requirements for maternity hospital stays and prohibits insurers from requiring authorization.

(b) Determining services subject to precertification – Outpatient: factors for adding a service to the MPL

Factor	Applicable to M/S	Applicable to MH/SUD
Cost of treatment	✓	✓
Variability in cost and practice	✓	✓
Patient safety	✓	✓
Clinical quality control	✓	✓
Marked variation in provider utilization patterns	✓	✓
Incorrect utilization	✓	✓
Application of Clinical Policy Bulletin (CPB) requirements	✓	✓
Standards of industry practice	✓	✓
Return on investment	✓	✓

- **Cost of treatment** is the measurement of the cost of an M/S or MH/SUD service. The **evidentiary standard and sources** upon which this factor is based are:
    - The average Medicare rate of at least $150, meaning that a service may be added to the MPL if its average Medicare rates is at least that amount.
    - Aetna's national paid Medicare claims experience.

- **Variability in cost and practice** is the measurement of variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period. The **evidentiary standards and sources** upon which this factor is based are:
    - Claims data that demonstrates a greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment.
    - Internal Aetna claims data for M/S and MH/SUD services.

- **Patient safety** refers to whether precertification can minimize potential harm to a member, particularly for life changing procedures that are irreversible post-surgery. The **evidentiary standards and sources** upon which this factor is based are:
    - Evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.

- The most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found in various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

- **Clinical quality control** refers to efforts to verify a provider and proposed treatment are qualified and appropriate so that the possibility of adverse outcomes is reduced. The **evidentiary standards and sources** upon which this factor is based are:
  - Evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
  - The most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

- **Marked variation in provider utilization patterns** means the existence of a significant range in providers' utilization of the service, drug or device, suggesting that some of the utilization may be unnecessary. The **evidentiary standards and sources** upon which this factor is based are:
  - The review of trends in provider utilization patterns and procedure codes for services that providers furnish, and how those trends align with clinical guidelines.
  - Utilization as a company, competitor information, and vendor input.

- **Incorrect utilization** is the potential that a given service, drug or device is not appropriate for the member's condition. The **evidentiary standards and sources** upon which this factor is based are:
  - Evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies.
  - The most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer

Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

- **Application of Clinical Policy Bulletin (CPB) requirements** refers to the opportunity to make determinations required under Aetna's CPBs and other clinical policies pertaining to the experimental, investigational, or unproven nature of a service, appropriate use of new or changing technology, step therapy, or site of service. The **evidentiary standards and sources** upon which this factor is based are:
    - The large number of analyses and conclusions contained within the CPBs.
    - Evidence-based and peer reviewed literature referenced within said CPBs.

- **Standards of industry practice** are what other health insurers and administrators have decided to be appropriate in terms of precertification. The **evidentiary standards and sources** upon which this factor is based are:
    - Publicly available information from competitors and public health organizations such as the Centers for Disease Control and Prevention (CDC) and U.S. Department of Health and Human Services (HHS).
    - Competitor analysis to determine whether precertification is appropriate for a given service at a given time (e.g. during a public health emergency).

- **Return on Investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs. The **evidentiary standards and sources** upon which this factor is based are:
    - A forecasted ROI of at least 3:1, based on anticipated out-of-network utilization costs.
    - A calculation based on internal claims data and administrative cost data: (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service.

(c) Determining services subject to precertification – Outpatient: factors for removing a service from the MPL

Factor	Applicable to M/S	Applicable to MH/SUD
Return on investment	✓	✓

- **Return on Investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs. The **evidentiary standard and sources** upon which this factor is based are:
    - Actual ROI (based on actual out-of-network utilization) that is less than 3:1.
    - A calculation based on internal claims data and administrative cost data: (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service.

In addition, an M/S or MH/SUD service may be removed if the other factor(s) noted above that warranted including the service on the MPL are no longer present.

(d) Factors for the process of precertifying services (inpatient and outpatient)

Factor	Applicable to M/S	Applicable to MH/SUD
NCQA Guidelines and Standards	✓	✓
Generally accepted standards of medical practice and clinical appropriateness	✓	✓
Applicable state and federal law	✓	✓

- **National Committee for Quality Assurance (NCQA) Accreditation Standards -** NCQA sets utilization management standards for Health Plan accreditation and Managed Behavioral Health Organization accreditation. The **evidentiary standards and sources** upon which this factor is based are:
    - Timeliness and clinical review standards that Aetna sets to meet NCQA Guidelines and Standards, as implemented through Aetna policies NCS 503: Medical Review P&P and NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P.
    - NCQA Health Plan Accreditation and MBHO Utilization Management Standards and Guidelines: Clinical Criteria for UM Decisions, Appropriate Professionals, Timeliness of UM Decisions, and Clinical Information.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in clinical policies. In general, the following **sources** contain the **evidentiary standards** (i.e., clinical treatment guidelines) utilized by Aetna's clinicians during the precertification determination process:
    - Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)

- MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
- National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

- **Applicable state and federal law** are regulatory and legal requirements concerning the precertification process. The **evidentiary standards and sources** upon which this factor is based are:
  - Time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations, as implemented through Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P.
  - Timeframes set forth in applicable state law for insured plans, that require certain turnaround times for precertification decisions in some states. State law or regulation that mandates a more stringent response time supersedes Aetna's national standard and is acknowledged in state amendments to the corresponding NCS P&Ps.
  - Specific medical necessity guidelines set forth in applicable law. Insured plans in a state that requires use of specific medical necessity guidelines are administered in accordance with the state's requirements, and are acknowledged in state amendments to the corresponding NCS P&Ps.
  - Other applicable state law requirements pertaining to precertification.

Step 3: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Cost management** is a factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management applies equally to all M/S and MH/SUD benefits. Cost management generally underlies Aetna's determination that M/S and MH/SUD inpatient services require precertification. For M/S and MH/SUD outpatient services subject to a precertification requirement, cost management aligns directly to the terms "cost of treatment," "variability in cost and practice," and "ROI" defined and identified above in Step 2 and more fully below in Step 3, Part 2.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: With respect to cost management, the evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. Since Aetna's entrance into the insurance and health plan administration business, cost management has been and continues to be a significant operating consideration. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (*see, e.g.,* Form 10-K at page 34 "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . .

medical management programs."). This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of precertification, cost management does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

- **Clinically appropriate utilization** is a factor and strategy underlying the design of precertification, seeking to ensure the plan covers medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In accordance with Aetna's standard certificate of coverage, medically necessary health care services are those that are clinically appropriate in terms of type, frequency, extent, site, place of service, duration, and considered effective for the member's illness, injury, or disease.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of clinically appropriate utilization applies equally to all M/S and MH/SUD benefits. This design factor aligns to the use of uniform evidentiary standards to assess the clinical appropriateness of a particular service, discussed in more detail below.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards considered and relied upon when designing this NQTL are those generally accepted standards of care identified above in Step 2, Part 1 (e.g., MCG, LOCUS, CALOCUS). For M/S benefits, the assessment of whether care is clinically appropriate in the context of precertification relies on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins when determining what is clinically appropriate utilization. For MH/SUD benefits, clinically appropriate is based on the American Society of Addiction Medicine (ASAM) Criteria: *Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), Aetna's Applied Behavioral Analysis Medical Necessity Guide, and the appropriate Aetna MH/SUD Clinical Policy Bulletins. Please see Aetna's Medical Necessity NQTL Comparative Analysis for a detailed analysis of the factors, evidentiary standards and sources relied upon to adopt Aetna's medical necessity criteria.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of precertification, clinically appropriate utilization does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of clinically appropriate utilization, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: As noted above, the factors of cost management and clinically appropriate utilization apply equally and agnostically to both M/S and MH/SUD benefits in the general design of precertification. They are interrelated because they collectively seek to ensure that the plan covers only medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective precertification process. Similarly, no one factor is weighted more than another in the design of precertification.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in the application of precertification for: (a) determining services subject to precertification-inpatient, (b) determining services subject to precertification - outpatient: adding a service to the MPL, (c) determining services subject to precertification- outpatient: removing a service from the MPL, and (d) for those services for which precertification is required, the process for precertifying services (inpatient and outpatient).

(a) Determining services subject to precertification - Inpatient

- **Place of service** refers to an inpatient admission to a hospital or other healthcare facility (e.g. skilled nursing facility, rehabilitation facility, or residential treatment facility), usually requiring an overnight stay and including room, board, and general nursing care.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Where a service has an inpatient place of service, precertification is required, except for the limited circumstance addressed below.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: Place of service is established upon admission to a facility; inpatient admissions as identified by the type of bill code on the claim submission require precertification. The type of bill is a 4-digit code on the UB-04 claim form, as specified by the National Uniform Billing Committee (NUBC). Inpatient claims are identified as:

i. 011x – Inpatient hospital
ii. 021x – Inpatient skilled nursing facility
iii. 0115 – Hospice Room and Board - Private
iv. 0125 – Hospice Room & Board – Semi-private

Revenue codes are used for MH/SUD inpatient claims. The NUBC also defines and maintains these:

v. 100x – Behavioral Health Accommodations
vi. 1000 – Behavioral Health Accommodations-General
vii. 1001 – Behavioral Health Accommodations-Residential Psychiatric
viii. 1002 – Behavioral Health Accommodations–Residential Chemical Dependency
ix. 1003 – Behavioral Health Accommodations – Supervised Living
x. 1004 – Behavioral Health Accommodations – Halfway House
xi. 1005 – Behavioral Health Accommodations – Group Home

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to inpatient MH/SUD and M/S benefits.

- **Federal law** consists of regulatory and legal requirements concerning precertification requirements for inpatient services.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Where applicable federal law would prohibit Aetna from requiring precertification for an inpatient stay, Aetna complies with the applicable legal requirements and does not require precertification.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** In this context, the applicable evidentiary standard is the NMHPA, which sets minimum length of stay requirements for maternity hospital stays. Pursuant to the NMHPA, a health plan must provide inpatient maternity coverage for a mother and her newborn child for a minimum of 48 hours (2 days) following a normal vaginal delivery, and a minimum of 96 hours (4 days) following a Cesarean section delivery. The health plan cannot require the attending physician to obtain authorization from the plan for prescribing the 48/96-hour minimum stay.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to inpatient MH/SUD and M/S benefits.

***Relationship, ordering, and weighting of multiple factors*:** The factors of place of service and applicable federal law are interrelated. However, federal law is weighted, because if there is a

maternity/newborn admission claim, prior authorization cannot be required regardless of the place of service. As applied, both factors result in Aetna requiring precertification for inpatient admissions for M/S and MH/SUD benefits, except where federal law prohibits such a requirement.

(b) Determining services subject to precertification – Outpatient: factors for adding a service to the MPL

An M/S or MH/SUD service must meet one or more of the following bulleted factors below to be added to the MPL: cost of treatment, variability in cost and practice, patient safety, clinical quality control, marked variation in provider utilization patterns, incorrect utilization, application of CPB requirements, and/or standards of industry practice. In addition, as explained below, a forecasted ROI of at least 3:1, based on anticipated out-of-network utilization costs, is expected. The below discussion addresses these factors and how they are used in the application of precertification. These are the factors that apply to determine whether to add an outpatient service to the MPL and thereby subject the service to precertification. However, **no** M/S or MH/SUD services were considered or added to the MPL in 2025. Therefore, Aetna does not have a specific listing of how the factors listed below were applied to services for addition to the MPL in 2025.

- **Cost of treatment** is the measurement of the cost of an M/S or MH/SUD service.
  (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. As a general matter, an M/S or MH/SUD service may be added to the MPL if the average paid Medicare rate for a service is at least $150 based on Aetna's national paid Medicare claims experience. Cost of treatment is a factor reviewed by Aetna's Policy and Plan Design Committee (PPDC) when deciding whether to add a service to the MPL. The PPDC oversees the terms of Aetna's standard certificates of coverage and any changes to them, including changes to the MPL. PPDC members and business partners such as Product and Sales/Account Management may propose changes to the MPL. The PPDC is responsible for voting on proposed additions to the NPL, based on consideration of all of the factors identified in Step 2, including cost of treatment.

  The PPDC is comprised of clinicians, product managers, compliance leads, and other subject matter experts representing both Behavioral Health and Medical expertise. The senior Vice President of Office of the Chief Medical Officer or designee will appoint a physician to chair the PPDC. The PPDC Chair approves voting members, which include medical directors and other representatives from Medical Policy & Program Solutions, Medical Policy Physicians, Medical Affairs, Behavioral Health, Business Compliance, Claim & Call Policy, Network Strategy & Performance Management, National Quality Management, Health Operations Policy Process,

Medical Economics, Pharmacy, Product Development, Product & Regulatory Approvals, Student Health, and the Mental Health Parity Team.

The voting members may collaborate and solicit input from key business partners to assure delivery of a consistent guideline of high quality. Business partners include, but are not limited to, representation from Medical Policy Operations Coding, Medical Policy & Program Solutions, Business Compliance, Health Operations Policy Process, National and Regional Network, and Operation Leads. The Policy and Plan Design Committee Composition is included in Appendix E.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standard that is relied upon when applying this factor is the average paid Medicare rate of at least $150, meaning that a service may be added to the MPL if its national average Medicare rate is at least that amount.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost of treatment, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits

- **Variability in cost and practice** is the measurement of variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. An M/S or MH/SUD service may be added to the MPL if internal claims data demonstrates that there is greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including variability in cost and practice. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standard considered or relied upon in applying this factor is internal Aetna claims data that demonstrates a greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment, in the most recent 12-month period. A service has a three-fold variability if the maximum value divided by the minimum value is greater than three. For example, if the cost per unit for a specific service within a 12-month period ranges between $100 and $350, the variability is 3.5 (3.5 = 350/100). Similarly, the variability in the range

of the length of treatment and overall number of services per treatment are calculated the same way.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of variability in cost and practice, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Patient safety** considers whether precertification can minimize potential harm to a member, particularly for life changing procedures that are irreversible post-surgery.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A service may be added to the MPL if the PPDC determines that precertification for a service, drug or device can minimize potential harm to a member, particularly for life changing procedures that are irreversible post-surgery. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including patient safety. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor are evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies. These nationally recognized guidelines include the most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics).

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of patient safety, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Clinical quality control** refers to efforts to verify a provider and proposed treatment are qualified and appropriate so that the possibility of adverse outcomes is reduced.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A service may be added to the MPL in order to verify a provider and proposed treatment are qualified and appropriate so that the possibility of adverse outcomes is reduced. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including clinical quality control. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor are evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies. These nationally recognized guidelines include the most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.
    (d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of clinical quality control, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Marked variation in provider utilization patterns** is the existence of a significant range in providers' utilization of the service, drug, or device, suggesting that some of the utilization may be unnecessary.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL:*** This factor applies equally to M/S and MH/SUD services. A service may be added to the MPL if there is a significant range in providers' utilization of the service, drug or device, suggesting that some of the utilization is unnecessary. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including marked variation in provider utilization

patterns. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor are the review of trends in provider utilization patterns and procedure codes for services that providers furnish, and how those trends align with clinical guidelines. Utilization data reviewed for trends and patterns may come from internal Aetna data, competitor information, or vendor input, as available.

(c) ***If the factor depends on specific decisions made in the administration of benefits:*** The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There is no deviation or variation from the factor marked variation in provider utilization patterns, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Incorrect utilization** is the potential that a given service, drug, or device is not appropriate for the member's condition.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A service may be added to the MPL if there is the potential that a given service, drug or device is not appropriate for a particular condition. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including incorrect utilization. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor are evidence-based clinical practice and preventive services guidelines from nationally recognized sources that promote consistent application of evidence-based treatment methodologies. These nationally recognized guidelines include the most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health Care Guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins. Evidence-based guidelines can be found on various nationally recognized sources, including medical societies and associations (American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Medical Association, American College of Cardiology, American Diabetes Association, American Academy of Pediatrics, and so on).

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of the factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There is no deviation or variation from the factor of incorrect utilization, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Application of Clinical Policy Bulletins (CPBs)** is the opportunity to make determinations required under Aetna's CPBs and other clinical policies pertaining to the experimental, investigational, or unproven nature of a service, appropriate use of new/changing technology, step therapy, or site of service.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A service may be added to the MPL if there is the opportunity to make determinations required under Aetna's CPBs and other clinical policies pertaining to the technology, step therapy, or site of service. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including application of CPBs. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor are the large number of analyses and conclusions referenced within the CPBs. Please see Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis for additional detail on the CPB development and review process.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of application of clinical policy bulletins, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Standards of industry practice** considers what other health insurers and administrators have decided to be appropriate in terms of precertification.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A service may be added to the MPL based upon consideration of whether other health insurers and administrators have decided that a service is appropriate in terms of precertification. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including standards of industry practice. Please see

the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor are publicly available information and competitor analysis to determine whether precertification is appropriate for a given service at a given time (e.g., during a public health emergency).

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There is no deviation or variation from the factor of standards of industry practice, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Return on Investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A forecasted ROI of at least 3:1, based on anticipated out-of-network utilization costs (including penalty amounts for failure to precertify), is expected for a service to be added to the MPL. The PPDC is responsible for voting on proposed additions to the MPL, based on consideration of the factors identified in Step 2, including ROI. Please see the discussion above concerning the PPDC's composition and the structure of its deliberative process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standards considered or relied upon in applying this factor is a forecasted ROI of at least 3:1, based on anticipated out-of-network utilization costs. There are two variables in the ROI calculation: (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service. ROI is calculated by dividing (i) by (ii). The 3:1 ROI threshold has been utilized by Aetna for many years as part of its assessment of whether potential cost-containment initiatives warrant implementation and are deemed appropriate for purposes of adding, retaining or removing services, drugs and devices on the MPL. A service, drug or supply may be added to the MPL if it does not have a forecasted ROI of at least 3:1, but one or more of the factors above (cost of treatment, variability in cost and practice, patient safety, clinical quality control, marked variation in provider utilization, application of Clinical Policy Bulletins, standards of industry practice) are met.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the ROI factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: For both M/S and MH/SUD services, to be added to the MPL, a service must meet one or more of the factors of cost of treatment, variability in cost and practice, patient safety, clinical quality control, marked variation in provider utilization, application of Clinical Policy Bulletins, or standards of industry practice. These factors are weighted equally. In addition, a forecasted ROI of at least 3:1 is expected, but is not required.

(c)Determining services subject to precertification – Outpatient: factors for removing a service from the MPL

For both MH/SUD and M/S services, the PPDC may decide to remove a service from the MPL based on the factors below. However, no M/S or MH/SUD services were considered for removal or removed from the MPL in 2025. Therefore, Aetna does not have a specific listing of how the factors listed below were applied to services for consideration of removal from the MPL in 2025.

- **Return on Investment (ROI)** is the health care cost expense savings related to appropriate denials of non-medically necessary care divided by administrative costs.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. A service, drug or device may be removed from the MPL if the actual ROI (based on actual out-of-network utilization) is less than 3:1 and/or if the other factor(s) that warranted including the service on the MPL are no longer present. Application of the factor depends on evaluation conducted by the PPDC. Please see the discussion above concerning the PPDC composition and processes.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the factor***: The evidentiary standard considered or relied upon in applying this factor is the actual ROI based on actual out-of-network utilization is less than 3:1. The ROI is calculated as described above, using two variables: (i) gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) gross dollar amount of costs to administer precertification for that service. ROI is calculated by dividing (i) by (ii). The 3:1 ROI threshold has been utilized by Aetna for many years as part of its assessment of whether potential cost-containment initiatives warrant implementation and are deemed appropriate for purposes of adding, retaining or removing services, drugs and devices on the MPL.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The application of this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: For both M/S and MH/SUD services, the PPDC may decide to remove a service, drug, or device from the MPL if the actual ROI (based on actual out-of-network utilization) is less than 3:1 and/or if the factors of cost of treatment, variability in cost and practice, patient safety, clinical quality control, marked variation in provider utilization, application of CPBs, standards of industry practice that warranted including the service on the MPL are no longer present. For any services evaluated for removal from the MPL, the ROI factor would be considered before applying the other factors; however, no factor is weighted more heavily than another.

(d) Factors for the process of precertifying services (inpatient and outpatient)

For M/S and MH/SUD inpatient benefits, and those benefits in the outpatient–all other classification for which precertification is required, the below discussion addresses the factors that are applied to the process of precertifying services.

- **National Committee for Quality Assurance (NCQA) Accreditation Standards -** NCQA sets utilization management standards for Health Plan accreditation and Managed Behavioral Health Organization accreditation.

(a) ***How the factor is used to determine which benefits are subject to the NQTL*:** This factor applies equally to M/S and MH/SUD services. Aetna uses NCQA Health Plan and Managed Behavioral Health Organization Utilization Management Standards and Guidelines to set policies and procedures for the process of precertifying inpatient and outpatient M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL*:** NCQA Standards and Guidelines require timeliness standards for precertifying services on the NPL. Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy & Procedure establishes the timeliness standards for urgent and non-urgent precertification requests that apply equally to M/S and MH/SUD services subject to precertification. These standards are outlined in Step 4, Part 2, and are contained in Attachment A of NCS 504. These standards are compliant with NCQA accreditation requirements for precertification, concurrent review and retrospective review. Additionally, the NCQA Standards and Guidelines include requirements pertaining to the clinical criteria used in decision making, the review of relevant medical records, and the involvement of appropriate personnel in decision making. These requirements are implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure and are discussed in detail in Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis.

(c) ***If the factor depends on specific decisions made in the administration of benefits*:** This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor*:** There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in clinical policies.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to determine whether to authorize coverage for M/S and MH/SUD preauthorization requests.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon are the following guidelines utilized by Aetna's clinical staff during the precertification determination process:

- Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
- MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
- National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff draw upon their training and expertise in applying clinical

review criteria/guidelines to determine whether to authorize coverage for M/S and MH/SUD precertification requests. This necessarily involves individualized evaluations and determinations for each member and request for coverage. Please see Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis for further detail. Additionally, information regarding the nature and timing of the decisions, as well as the designations and qualifications of the clinical staff is included herein in Step 4, Part 2. When making precertification decisions for M/S services, Aetna's clinical staff rely on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. Similarly, when making precertification decisions for MH/SUD services, Aetna's clinical staff rely on American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Aetna's Applied Behavioral Analysis Medical Necessity Guide, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), and the appropriate Aetna MH/SUD Clinical Policy Bulletins. Staff are required to document the specific clinical guidelines relied upon when making benefit determinations within their documentation notes.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of generally accepted standards of medical practice and clinical appropriateness, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Applicable state and federal law** are regulatory requirements related to the timeframes, use of specific medical necessity criteria, or other requirements applicable to precertification.

(a) ***How the factor is used to determine which benefits are subject to the NQTL*:** This factor applies equally to M/S and MH/SUD services. Aetna complies with applicable state and federal required timeframes for precertifying services. Aetna's NCS 504 Policy establishes national standard timeframes which comply with time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations. Aetna's NCS 503 Policy sets forth the medical necessity criteria used in reviewing precertification requests. State law or regulation that mandates a more stringent response time, use of specific medical necessity criteria, or other requirements applicable to precertification, supersedes Aetna's national standards.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL:*** The evidentiary standards relied upon are timeframes, specific medical necessity criteria, or other standards that comply with applicable state and federal requirements for precertification requests. These standards are reflected in NCS 504 and NCS 503, and the state specific amendments to NCS 504 and 503.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of applicable state and federal law, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering and weighting of multiple factors: The factors listed above apply to distinct aspects of the process of performing precertification, including decision-making and the timeliness and medical necessity standards applicable thereto. The factors are interrelated, and all operate together to ensure that Aetna employs an appropriate and effective precertification process. Aetna's national standards discussed above and set forth in NCS policies and procedures are based upon NCQA accreditation requirements and generally accepted standards of medical practice and clinical appropriateness. However, applicable law is weighted more heavily, as applicable law or regulation that mandates a more stringent response time, mandates use of specific medical necessity criteria, or other requirements applicable to precertification, supersedes Aetna's national standards for applicable plans.

<u>Step 4</u>: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, for out-of-network benefits, Aetna conducts precertification for inpatient admissions and certain outpatient services and supplies. Accordingly, precertification applies to the following out-of-network benefit classifications: 1) inpatient and 2) outpatient–all other. As noted in Step 2, Part 1, two factors were used in the context of designing precertification: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Promotion of cost management and clinically appropriate utilization are general design factors and are the basis and rationale underlying Aetna's policies related to precertification requirements. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, both factors apply equally to both benefit types.

These general design factors are evidenced through general acknowledgement of cost management as a factor in CVS Health public filings noted in Step 3, Part 1, and the specific clinical guidelines identified in Step 2, Part 1, that reflect the clinically appropriate guidelines for both M/S and MH/SUD services. Additionally, Aetna's **UM Program Description** provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." While these materials evidence the general

design factors of promotion of cost management and clinically appropriate utilization, there is no written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of precertification with respect to M/S and MH/SUD benefits.

These factors apply equally to both benefit types and are not applied incomparably, or more stringently, to MH/SUD benefits in either the inpatient or outpatient–all other benefit classifications. Similarly, there are no deviations or variations from these two factors as they apply to the design of precertification. Aetna's analysis shows that as written, the processes, strategies, evidentiary standards or other factors used in designing precertification with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing precertification with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, for out-of-network benefits, precertification applies to the following benefit classifications: 1) inpatient and 2) outpatient–all other. As noted in Step 2, Part 2, different factors are applied in the context of precertification for: (a) determining services subject to precertification- inpatient; (b) determining services subject to precertification- outpatient: adding a service to the MPL; (c) determining services subject to precertification- outpatient: removing a service from the MPL; and (d) for those inpatient and outpatient services for which precertification is required, the process for precertifying services. This section demonstrates that as written, the processes, strategies, evidentiary standards and other factors used in applying precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying precertification to M/S benefits in the applicable benefit classifications.

(a) Determining services subject to precertification – Inpatient

As set forth in Step 2, Part 2, the factors used in the application of precertification, to determine out-of-network inpatient services subject to precertification, are 1) place of service and 2) federal law. As written, for both M/S and MH/SUD, precertification applies to all inpatient admissions except where federal law probits a precertification requirement. Specifically, maternity and newborn admissions within the standard length of stay do not require precertification according to the NMHPA; the health plan must automatically provide benefits for a hospital stay following delivery without requiring precertification. For stays that extend beyond the 48/96-hour minimum stay, authorization is required. Aetna's analysis of applicable written materials

demonstrates that the processes, strategies, evidentiary standards or other factors used to apply precertification to inpatient MH/SUD benefits are comparable to, and no more stringently applied than, those used to apply precertification to M/S benefits.

Per Aetna's standard certificate of coverage and **NCS 100: Precertification Policy**, precertification applies to inpatient admissions. The MPL, within the certificate of coverage, memorializes Aetna's determination that all inpatient admissions, whether M/S or MH/SUD, require precertification except for maternity and newborn admissions that are within the standard length of stay. Aetna uses the factors of place of service and applicable law, which are applied comparably to support the written policies which establish that all inpatient services, except where federal law requires otherwise, are subject to precertification. The place of service for a particular service is determined based on guidance of the National Uniform Billing Committee, which is the governing body for forms and codes used in facility bills. This guidance is used for both M/S and MH/SUD to establish inpatient status such that prior authorization is required. Aetna applies applicable law in determining which services are/are not subject to prior authorization, which in this instance includes the NMHPA.

The factors of place of service and federal law are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of precertification to MH/SUD inpatient benefits. Regardless of whether the inpatient admission is for an M/S or MH/SUD condition, unless the admission cannot be subject to precertification due to federal law (the NMHPA), precertification is required. Both considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material used to apply precertification and determine which inpatient benefits are subject to precertification shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(b) Determining services subject to precertification – Outpatient: adding a service to the MPL

As noted in Step 2, Part 2, an M/S or MH/SUD service must meet one or more of the following criteria in order to be added to the MPL: cost of treatment, variability in cost and practice, patient safety, clinical quality control, marked variation in provider utilization patterns, incorrect utilization, application of CPB requirements and/or standards of industry practice. Each of these factors is reflected in the **MPL Policy and Procedure** which applies, as written, equally to M/S and MH/SUD services. In addition, a forecasted ROI of at least 3:1, based on anticipated out-of-network utilization costs, is expected. Again, this factor applies, as written in the MPL Policy and Procedure, equally to M/S and MH/SUD services. Importantly, Aetna maintains one MPL Policy and Procedure which applies equally to M/S and MH/SUD benefits in deciding which services to add to the MPL.

The member's certificate of coverage identifies what out-of-network outpatient services, if any, require precertification under the health plan and what, if any, are the penalties for not obtaining precertification. As written in the MPL Policy and Procedure, the PPDC oversees the terms of Aetna's standard certificates of coverage and any changes to them, including changes to the MPL. PPDC members and business partners such as Product and Sales/Account Management may propose changes to the MPL. For any proposed changes, the PPDC votes on whether to approve a change. The MPL P&P provides that the PPDC is to consider the factors listed in Step 2, Part 2, in deciding whether to add services, drugs, or devices to the MPL.

The PPDC is comprised of clinicians, product managers, compliance leads and other subject matter experts representing both Behavioral Health and Medical expertise. The PPDC has numerous responsibilities relating to policy and plan design, including responsibility for maintaining the MPL. As written in the MPL P&P, the PPDC Committee meetings will be held approximately quarterly at the call of the PPDC Chair, or designee, who shall also approve the agenda. Each PPDC meeting addresses one or more policy and/or plan design topics. Ad hoc discussion topics are submitted to and approved by the Chair. The PPDC Chair and Facilitator establish that a quorum of voting members is in attendance at the initiation of the call. A quorum is defined as a majority of the voting members, and meetings are presided over by the PPDC Chair, or designee. The PPDC Composition is included in Appendix E.

The factors discussed herein are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of precertification to MH/SUD outpatient–all other benefits. The same considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material (i.e., the MPL Policy and Procedure) used to apply precertification and determine whether to add a service to the MPL shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services than to M/S services, particularly because no M/S or MH/SUD services were added to the MPL in 20245. Further, no new M/S or MH/SUD services have been added to the MPL in the past 8 years.

(c) Determining services subject to precertification - Outpatient: removing a service from the MPL

As written pursuant to the **MPL Policy and Procedure,** for M/S and MH/SUD services, the PPDC may decide to remove a service, drug, or device from the MPL if the actual ROI (based on actual out-of-network utilization) is less than 3:1 and/or if the other factor(s) that warranted including the service on the MPL are no longer present. The factor of ROI and its associated evidentiary standard and sources identified in Step 2, Part 2 are identified in the MPL Policy and Procedure as the primary factor for removing M/S and MH/SUD services from the MPL. The factor of ROI, as written, applies equally to M/S and MH/SUD services. Also, per the written

policy, the same underlying evidentiary standard and sources (i.e., 3:1 ROI and internal claims and administrative cost data) are applicable to M/S and MH/SUD services. Pursuant to the MPL Policy and Procedure, the PPDC may also look at whether the factors that warranted adding a service (noted above) to the MPL are still present. Again, as written, these factors and evidentiary standards and sources apply equally to M/S and MH/SUD services.

As written, the factors discussed herein are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of precertification to MH/SUD outpatient–all other benefits. The same considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material (i.e. the MPL Policy and Procedure) used to apply precertification and determine whether to remove a service from the MPL shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(d) The process of precertifying services (inpatient and outpatient)

As set forth above in Step 2, Part 2, the factors used in application, for the process of precertifying services (inpatient and outpatient) are: 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law. These factors support Aetna's written processes for precertifying services that are on the MPL. These processes are described in detail in the Aetna National Clinical Services (NCS) Utilization Management policies and procedures pertaining to precertification. Aetna maintains one set of written UM precertification policies that are equally applicable to M/S and MH/SUD services and represent the strategies and processes Aetna employs to precertify out-of-network M/S and MH/SUD services:

- NCS 100: Precertification Policy & Procedure
- NCS 503: Medical Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure – VA amendment
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy – VA amendment
- NCS 505: Denial of Coverage Policy and Notification
- NCS 505: Denial of Coverage Policy and Notification – VA amendment
- NCS 506: Peer-to-Peer Review Policy
- NCS 506: Peer-to-Peer Review Policy – VA amendment
- NCS 510: Internal Quality Review Policy

Each of these policies is discussed in turn below, demonstrating that they are comparably applied, as written, to M/S and MH/SUD services.

NCS 100 defines precertification and establishes the rules and processes for applying clinical criteria/guidelines to covered benefits for eligible members during the pre-service review process. As noted in the scope of the policy, this applies to M/S (called precertification) and MH/SUD (called behavioral health). Precertification includes confirming the member's eligibility, assessing medical necessity, pre-service discharge planning, determination of coverage and communication of coverage decisions to treating practitioners and members, and documentation of determinations to support accurate and timely claims adjudication.

The procedure section of **NCS 100** details how precertification requests are administered. In brief, for M/S and MH/SUD services, precertification requests and supporting documentation are reviewed to verify member eligibility, the provider's network participation status, and the availability of benefits. Clinical support staff can issue administrative denials (due to member's lack of eligibility or benefit plan exclusions, for example). Coverage decisions that require clinical review are performed by licensed clinicians (e.g., Registered Nurse (RN), licensed clinical social worker (LCSW), licensed behavior analyst (LBA), licensed professional counselor (LPC)). The clinical precertification review follows the review procedure detailed in NCS 503, which is listed as a related material in the NCS 100 policy. The "as written" processes in NCS 100 used to review precertification requests are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. While NCS 100 refers to separate UM units that handle M/S and MH/SUD requests, the processes followed by those units are comparable and no more stringently applied to MH/SUD.

NCS 503 establishes the process of medical review and establish the written clinical criteria/guidelines used by Aetna's clinicians in making medical necessity determinations. This Policy applies equally to M/S and MH/SUD services. For both M/S and MH/SUD services, the guiding strategy behind precertification relies upon the clinical reviewers' exercise of their clinical judgment, guided by clinical criteria, to determine whether to authorize coverage for precertification requests. While NCS 503 sets forth separate written guidelines that apply to M/S and MH/SUD services, all services are subject to appropriate guidelines based on industry standards and generally accepted standards of medical practice and clinical appropriateness. NCS 503 otherwise does not differentiate between M/S and MH/SUD services. The relevant specific written guidelines referred to in NCS 503 are:

- **LOCUS and CALOCUS/CASII (**MH/SUD) – Aetna uses the most current versions of LOCUS and CALOCUS/CASII, which are recognized nationally as a generally accepted standard of care tool, to guide clinicians in making medically necessary level of care determinations for mental health services. The Level of Care Utilization System (LOCUS) assessment was developed by the American Association of Community Psychiatrists (AACP) in 1996 to help determine the mental health care resource intensity needs of adults.

CALOCUS was developed was developed by the American Association of Community Psychiatrists in collaboration with the American Association of Child and Adolescent Psychiatry to help determine the mental health care resource intensity needs of children and adolescents.

- **ASAM** (MH/SUD) – Aetna uses the most current criteria published by the American Society of Addiction Medicine (ASAM) to guide clinicians in evaluating the medical necessity of levels and types of care for substance use disorders. ASAM Criteria are generally accepted, national standards for SUD treatment decisions and are recognized as such by many courts and regulators.

- **ABA Medical Necessity Guide** (MH/SUD) – Aetna's ABA medical necessity guidelines come from extensive review of the literature on the use of applied behavior analysis to treat autism spectrum disorder and a comparative review of the guidelines of other health insurers. A multidisciplinary committee of health care professionals within and external to Aetna Behavioral Health developed and approved the guidelines based on these reviews.

- **MCG Health Care Guidelines** (M/S) – Aetna uses the most current evidence-based Care Guidelines published by MCG Health to guide clinicians in making medically necessary level of care determinations for M/S services.

- **Aetna Clinical Policy Bulletins (CPBs)** (M/S and MH/SUD) – Aetna Clinical Policy CPBs describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's medical necessity decisions regarding specific M/S and MH/SUD services.

- **NCCN Clinical Practice Guidelines in Oncology** (M/S) – Aetna uses the most current clinical practice guidelines published by the National Comprehensive Cancer Network (NCCN) to make medical necessity determinations in oncology clinical reviews. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are comprised of recommendations for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines currently apply to more than 97% of cancers affecting patients in the United States. The NCCN Guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management.

    - **Section 38.2-3418.17 of the Code of Virgina –** Aetna uses the VA specific legislation to establish procedures around handling prior-authorization requests for individuals receiving treatment for an autism spectrum disorder and prior authorization for drugs prescribed for the treatment of a mental disorder listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

Regarding application of state law, state amendments to NCS 503 reflect state law requirements applicable to precertification, including limitations on precertification requirements and/or the use of alternative M/S and MH/SUD medical necessity guidelines as required by state law where applicable. Medical necessity guidelines do not replace professional judgment exercised by properly trained, licensed, and experienced clinicians and professionals who evaluate the provision of services in accordance with accepted standards of care. As explained in NCS 503, individual M/S and MH/SUD medical necessity determinations are afforded independent clinical consideration based on the member's presentation. As listed in NCS 503, staff considers the individual needs of the member when utilizing guidelines, including, but not limited to age, co-morbidities, complications, progress of treatment, need for skilled care, psychosocial situation, risk related to ethnicity or genetic factors and home environment, when applicable. Staff additionally considers the following characteristics of the local health care delivery system during the coverage determination process: the ability of the provider to meet the member's cultural and language needs, as appropriate; the availability of highly specialized services, such as detoxification facilities; the availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and, the ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition. NCS 503 further notes that approval decisions may be automated when appropriate. Automation uses clinical information submitted by the provider and compares it to Aetna's medical necessity criteria to render an approval decision, based on individualized clinical considerations, using the medical necessity guidelines outlined in NCS 503. For both M/S and MH/SUD medical necessity reviews, all adverse decisions are made by medical directors, never by automation or clinical staff who are not medical directors, as required by NCS 505: National Clinical Services Denial of Coverage Policy, discussed below. Thus, the "as written" material contained in NCS 503 pertaining to the medical review process is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 504 establishes the timeliness standards for urgent and non-urgent precertification determinations and notifications that apply equally to M/S and MH/SUD services. Attachment A to NCS 504 sets out timeliness standards for precertification decisions and notifications, separated into urgent precertification and non-urgent precertification requests. These timeliness standards apply equally to M/S and MH/SUD inpatient and outpatient precertification.

Urgent precertification requests

All MH/SUD inpatient admissions, including residential treatment center admissions, are considered urgent and follow the precertification determination timelines for urgent care in

accordance with the instructions contained in NCS 504 for urgent precertification requests. For commercial plans, Aetna follows the DOL/ERISA claims regulation definition of urgent care. Urgent care is defined by this regulation as any request for medical care or treatment to which the application of the time periods for making non-urgent care decisions:

- Could seriously jeopardize the life or health of the member or the member's ability to regain maximum function, based on a prudent layperson's judgment; or,
- In the opinion of a practitioner with knowledge of the member's medical condition, would subject the member to severe pain that cannot be adequately managed without the care or treatment that is the subject of the request; or,
- In the opinion of a practitioner with knowledge of the member's medical condition, the request is urgent.

Per NCS 504, initial determinations for urgent precertification requests are made within 72 hours of the request. If additional information is required to make a determination, Aetna will initiate the request for additional information within 24 hours of the receipt of the request. Aetna will notify requester of the determination (approval or denial) verbally within 72 hours of the receipt of the request. For approvals, a written notification will be sent upon request. For denials, if direct telephonic notification is provided within 72 hours from the receipt of the request, then the written notification must be sent within 3 calendar days of the telephonic notice. These timelines apply equally to M/S and MH/SUD services.

Non-urgent precertification requests

A non-urgent precertification request is one that does not meet the definition of urgent. Examples of M/S non-urgent requests include elective surgeries, such as a hysterectomy or bariatric surgery, or an electric wheelchair to replace a manual wheelchair. MH/SUD non-urgent requests are partial hospitalization, applied behavior analysis, and transcranial magnetic stimulation when they do not otherwise meet the urgent definition. Per NCS 504, initial determinations for non-urgent precertification requests are made within 15 calendar days of the request. If additional information is required to make a determination, Aetna will initiate the request for additional information within 15 calendar days of the receipt of the request. A verbal and/or written determination is issued within 15 calendar days of the receipt of all necessary clinical information.

Additionally, **NCS 505** defines and outlines the handling of denial of coverage determinations, including the responsibility for issuing clinical and administrative denial decisions, documentation requirements for denial decisions, and notification requirements for these coverage decisions. As written, this policy applies equally to M/S and MH/SUD services, which specifies that only M/S and MH/SUD medical directors can deny clinical coverage decisions. Because the processes are the same, the "as written" material contained in NCS 505 pertaining to the handling of coverage determination denials is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 506 outlines the peer-to-peer review process through which a treating practitioner, a clinician on behalf of the treating practitioner (e.g., genetic counselor for BRCA precertification requests) or a physician on behalf of a facility (for precertification denials) may request a discussion with a peer reviewer (licensed health plan physician medical director) or behavioral health consultant psychiatrist/psychologist/board certified behavior analyst-doctoral (BCBA-D), to discuss a clinical denial of coverage determination. Peer-to-peer is not an additional level of review or an appeal. It is a focused discussion between the provider representative and the peer reviewer. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D considers all available information when conducting a peer-to-peer review. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D reviews the applicable clinical criteria/guidelines in NCS 503, the clinical information that is present before and during the peer-to-peer discussion and uses clinical judgment to make a decision. For M/S, peer-to-peer reviews are conducted after a denial determination, upon request. For MH/SUD services, when clinically appropriate, peer-to-peer reviews are offered and conducted prior to the issuance of the initial coverage determination, in addition to peer-to-peer reviews that are available after a denial determination. As written, the process for peer-to-peer review is largely the same for M/S and MH/SUD, except that for MH/SUD services, Aetna may offer a peer-to-peer review before a determination has been issued, in addition to the peer-to-peer review that is available post-determination. Based upon the foregoing, the written material contained in NCS 506 pertaining to peer-to-peer review is comparably applied to MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

Finally, **NCS 510** describes Aetna's Internal Quality Review and Inter-Rater Reliability assessments. As written, the IQR/IRR process provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. Through inter-rater reliability (IRR) assessments, both M/S and MH/SUD medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria, and corrective actions are taken if the results do not meet certain metrics, which are the same for MH/SUD and M/S services. NCS 510 applies equally to M/S and MH/SUD services, and the processes set forth therein are the same for M/S and MH/SUD services. The "as written" processes in NCS 510, for evaluation of medical director and utilization management clinician accuracy and consistency, are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. The IRR results for both Behavioral Health and Medical clinicians are discussed in Step 5 and show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

The factors of 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law, are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently, as written, to MH/SUD benefits. Similarly, there are no deviations or variations in these

factors as they apply to the process of performing precertification. The written policies discussed above are based on these factors and are equally applicable to performing precertification for M/S and MH/SUD inpatient and outpatient–all other services. The factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material used to perform precertification shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

Aetna provides members with appeal rights when an adverse benefit determination is issued. When Aetna issues a denial of services or a reduction in coverage due to an EIU determination or blanket exclusion, that determination is considered an adverse benefit determination. Members have the right to request a review of that determination through the appeal process and may initiate an appeal by contacting Aetna.

Appeal rights and procedures are described in the COC under the section titled "Appeal of an Adverse Benefit Determination." The COC outlines the appeal process, including applicable timeframes, who may request an appeal on behalf of the member, how appeals are assigned and reviewed, and the options available if the member is not satisfied with the appeal decision. Aetna does not maintain separate appeal processes for MH/SUD services and M/S services; the same appeal procedures apply to both. In addition, once the internal appeal process has been exhausted, members may have the right to request an external review, as described in the COC. The COC also explains the circumstances under which external review may be available and the procedures for requesting it. The appeal and external review rights available to members are applied consistently for MH/SUD and M/S services and are not more stringent for MH/SUD services than for M/S services.

Summary

In sum, Aetna's analysis demonstrates that as written, the processes, strategies, evidentiary standards and other factors used in applying precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying precertification to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

** The quantitative data presented in this analysis is based on Aetna Life Insurance Company (ALIC) business, which represents approximately 74% of the total Virginia business. The NQTL processes, strategies, evidentiary standards, and other factors described herein are applied consistently across the relevant Virginia business. As a result, Aetna believes the ALIC data is representative of the operational application of the NQTL and provides a reliable basis for assessing compliance with MHPAEA's comparative analysis requirements and for supporting the findings and conclusions presented in this report.*

As noted in Step 1, for out-of-network benefits, precertification applies to the following benefit classifications: 1) inpatient and 2) outpatient–all other. As noted in Step 2, Part 2, different factors are applied in the context of precertification for: (a) determining services subject to precertification- inpatient; (b) determining services subject to precertification- outpatient: adding a service to the MPL; (c) determining services subject to precertification- outpatient: removing a service from the MPL; and (d) for those services for which precertification is required, the process for precertifying services. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying precertification to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying the precertification to M/S benefits.

(a) Determining services subject to precertification – Inpatient

In operation, precertification is required for inpatient admissions for both M/S and MH/SUD services except as noted above where federal law prohibits precertification. Thus, in operation, the factors, processes, strategies, and evidentiary standards used to determine which MH/SUD inpatient services are subject to precertification are comparable to, and are applied no more stringently than, the factors, processes, strategies and evidentiary standards with respect to M/S services.

(b) Determining services subject to precertification – Outpatient: adding a service to the MPL; and (c) Determining services subject to precertification– Outpatient: removing a service from the MPL

As noted previously in this analysis, the factors, evidentiary standards and sources that determine whether to add a new service to the MPL apply equally, and thus comparably, to M/S and MH/SUD services. A review and comparison of the MPL and number of M/S and MH/SUD services that require precertification, as well as how many services were added to the MPL in the prior year, further provides a basis to evaluate whether, in operation, the factors, evidentiary standards, and sources for determining services subject to precertification are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits.

For outpatient–all other benefits, based on a review of the MPL, there are 4 MH/SUD outpatient services subject to precertification compared to approximately 16 procedure groups of M/S outpatient services. Additionally, in 2025, the PPDC did not consider any M/S or MH/SUD services for addition to the MPL and did not add any such services to the MPL. Thus, in operation, the factors, processes, strategies, and evidentiary standards used to determine whether to add new MH/SUD services to the MPL are comparable to, and were applied no more stringently than, the factors, processes, strategies and evidentiary standards with respect to M/S services. Additionally, in operation, no M/S or MH/SUD services were considered for removal from the MPL or removed from the MPL in 2025. Thus, in operation, precertification is applied comparably, and not more stringently with respect to MH/SUD services.

(d) The process of precertifying services (inpatient and outpatient)

The data reflects the total number of decisions and the total number of decisions that were denied. The data is further broken down into administrative denials and medical necessity denials. This data is retrieved from Aetna's utilization management system. The data is separated out into the inpatient and outpatient–all other benefit classifications. Administrative denials are based on failure to meet plan administrative requirements, including the member's lack of eligibility, missing information required to complete the review, the benefits for the requested services are excluded under the member's plan, or the benefits have been exhausted under the member's plan. Medical necessity denials are denials for which the requested service did not meet the medically necessary criteria used by clinicians during the precertification process.

Denial Rates for Out-of-Network Precertification Requests
7/1/25-6/30/26

Out of-Network Precertification Decisions	Inpatient M/S	Inpatient MH/SUD	Outpatient All Other M/S	Outpatient All Other MH/SUD
Total Decisions	13	1	78	40
Denied Decisions	6	1	34	5
Overall Percent Denied	**46.15%**	**100.0%**	**43.59%**	**12.5%**
Total Administrative Denials	1	0	18	0
Percent Denied - Administrative	**7.69%**	**0.0%**	**23.08%**	**0.0%**
Total Medical Necessity Denials	5	1	16	5
Percent Denied – Medical Necessity	**38.46%**	**100.0%**	**20.51%**	**12.5%**

As demonstrated in Step 5, an in-operation review of out-of-network inpatient precertification determinations for VA ALIC business reflects a limited volume of MH/SUD precertification activity. Specifically, there was one out-of-network inpatient MH/SUD precertification determination, which resulted in a denial, compared to 13 out-of-network inpatient M/S determinations, of which 6 were denied. Accordingly, the overall denial rate was 100.0% for MH/SUD services (1 of 1 determination) and 46.15% for M/S services (6 of 13 determinations). The sole MH/SUD denial was based on medical necessity, resulting in a medical necessity denial rate of 100.0%, while the corresponding medical necessity denial rate for M/S services was 38.46% (5 of 13 determinations). No administrative denials were issued for MH/SUD services, compared to an administrative denial rate of 7.69% for M/S services (1 of 13 determinations). Given the extremely small MH/SUD sample size, consisting of a single determination, these results are not considered representative and do not provide a meaningful basis for concluding that the out-of-network inpatient precertification process is applied more stringently to MH/SUD services than to comparable M/S services.

Outpatient All Other As further demonstrated in Step 5, an in-operation review of out-of-network outpatient-all other precertification determinations for VA ALIC business indicates that denial rates for MH/SUD services were lower than those for M/S services. Specifically, there were 40 out-of-network outpatient-all other MH/SUD precertification determinations, of which 5 were denied, resulting in an overall denial rate of 12.5%. In comparison, there were 78 out-of-network outpatient-all other M/S precertification determinations, of which 34 were denied, resulting in an overall denial rate of 43.59%.

A review of denial reasons similarly reflects lower denial rates for MH/SUD services. No MH/SUD determinations were denied for administrative reasons, resulting in an administrative denial rate of 0.0%, compared to an administrative denial rate of 23.08% for M/S services (18 of 78 determinations). In addition, the medical necessity denial rate for MH/SUD services was 12.5% (5 of 40 determinations), compared to 20.51% for M/S services (16 of 78 determinations). Overall, these results indicate that the out-of-network outpatient-all other precertification process does not operate more stringently for MH/SUD services than for comparable M/S services.

Additionally, the IRR process described in NCS 510: Internal Quality Review Policy & Procedure provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. In that process, medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria. Corrective actions are taken if the results do not meet certain individual and business unit metrics, which are the same for M/S and MH/SUD. The IRR results for both Behavioral Health and Medical clinicians and medical directors show that the audits were performed as required and the overall goals met. Overall, the final score for M/S utilization reviews was 98%. For MH/SUD, the final score was 100%. These IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

Summary

In sum, review of the data addressed herein provides a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the precertification process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits. Based on the in-operation data and reviews discussed above, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying precertification with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying precertification with respect to M/S benefits in the applicable benefit classifications.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, out-of-network precertification is a pre-service utilization review performed by licensed healthcare professionals to determine medical necessity and appropriateness of treatment for certain M/S and MH/SUD services. Precertification applies to M/S and MH/SUD inpatient benefits, and those M/S and MH/SUD outpatient benefits listed on the MPL. As further demonstrated in Step 1, out-of-network precertification applies to the following benefit classifications: 1) out-of-network inpatient and 2) out-of-network outpatient–all other.

Step 2 identified the factors that are used to: 1) determine the inpatient services subject to precertification; 2) determine the outpatient services subject to precertification, pertaining to adding a service to the MPL; 3) determine the outpatient services subject to precertification, pertaining to removing a service from the MPL; and 4) how to apply precertification to inpatient and outpatient services. Step 3 explained the evidentiary standards and sources for those factors, and how they are used in the design and application of precertification. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD services. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD services subject to precertification and concluded that there are no written differences in that application that results in any MH/SUD services being treated more stringently than, or incomparably to, M/S services. Finally, Step 5 demonstrated that, in operation, inpatient and outpatient M/S and MH/SUD services are subject to precertification in a comparable manner. In the process of conducting

precertification, MH/SUD inpatient and outpatient services to which precertification applies are treated substantively and administratively in a comparable and no more stringent manner than M/S services.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors, evidentiary standards, and sources to M/S and MH/SUD benefits in determining which services require precertification and in conducting precertification. Two factors were used in the context of designing precertification: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits.

In the application of precertification, the factors used to determine inpatient services subject to precertification are 1) place of service and 2) federal law. Both in writing and in operation, precertification applies to all M/S and MH/SUD inpatient admissions except where prohibited by federal law. In the application of precertification, with respect to outpatient services, Aetna maintains one MPL Policy and Procedure which applies equally to M/S and MH/SUD benefits in deciding which services to add to or remove from the MPL, and the decisions are made by the same PPDC which includes both M/S and MH/SUD representation. As discussed above, an M/S or MH/SUD service must meet one or more of the following criteria to be added to the MPL: cost of treatment, variability in cost and practice, patient safety, clinical quality control, marked variation in provider utilization patterns, incorrect utilization, application of CPB requirements, and/or standards of industry practice. In addition, a forecasted ROI of at least 3:1, based on anticipated out-of-network utilization costs, is expected. Further, pursuant to the MPL Policy and Procedure, the same factors apply to M/S and MH/SUD services with respect to removal from the MPL. Finally, the factors used in application, for the process of precertifying services (inpatient and outpatient) are: 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law. These factors support Aetna's written processes for performing precertification. These processes are described in detail in the Aetna NCS utilization management policies and procedures pertaining to precertification. Aetna maintains one set of written UM precertification policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to perform precertification for M/S and MH/SUD inpatient and outpatient services. The factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Both in writing, and in operation, the same processes apply to conduct precertification for both M/S and MH/SUD services.

As demonstrated in Step 5, in operation, precertification is required for all inpatient admissions for both M/S and MH/SUD services except when prohibited by federal law. As for outpatient–all other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 16 procedure groups of M/S services. Similarly, an in-

operation review indicates that for 2025, no M/S or MH/SUD services were considered for addition or in fact added to the MPL, and no M/S or MH/SUD services were considered for removal or in fact removed from the MPL. From this information, Aetna may conclude that the factors, evidentiary standards, and sources used to determine which inpatient services require precertification and which outpatient services are added to or removed from the MPL are applied in a comparable, and not more stringent manner, for MH/SUD services.

As further demonstrated in Step 5, with respect to the precertification process, an in-operation review of out-of-network prior authorization determinations for VA ALIC business does not indicate that precertification is applied more stringently to MH/SUD services than to comparable M/S services. For inpatient services, there was one MH/SUD precertification determination, which resulted in a denial, compared to 13 M/S determinations, 6 of which were denied. While this resulted in an overall denial rate of 100.0% for MH/SUD services and 46.15% for M/S services, the MH/SUD result is based on a single determination and therefore does not provide a meaningful basis for comparison. For outpatient-all other services, the overall denial rate was significantly lower for MH/SUD services than for M/S services, at 12.5% (5 of 40 determinations) and 43.59% (34 of 78 determinations), respectively.

A review of denial reasons further supports this conclusion. For outpatient-all other services, the administrative denial rate was 0.0% for MH/SUD services, compared to 23.08% for M/S services. Similarly, the medical necessity denial rate was lower for MH/SUD services than for M/S services, at 12.5% and 20.51%, respectively. Although the sole inpatient MH/SUD determination was denied based on medical necessity, this result reflects only a single determination and is not representative of broader utilization patterns. Overall, based on the data evaluated, Aetna may conclude that the factors, evidentiary standards, and sources used to apply precertification are comparable for MH/SUD and M/S services and are not applied more stringently to MH/SUD services.

Additionally, an in-operation review of the IRR results for M/S and MH/SUD show that both Medical and Behavioral Health medical directors and clinicians are performing utilization management reviews accurately and consistently overall. The final overall score for M/S utilization reviews was 98%. For MH/SUD, the final overall score was 100%.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply precertification to MH/SUD benefits are comparable to, and are applied no more stringently than the processes, strategies, evidentiary standards, and other factors used in designing and applying precertification to M/S benefits across the applicable benefit classifications. Taken together with the favorable outcomes for MH/SUD at the book of business level, the precertification NQTL is

designed and applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Behavioral Health Medical Director, Quality and Mental Health Parity, Medical Doctor board certified in Psychiatry • Lead Director, Clinical Review Program Management • Manager, Health Services, Medical Policy and Program Solutions

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Nonquantitative Treatment Limitation Comparative Analysis:

CONCURRENT REVIEW

Step 1: Description of the NQTL [45 CFR 146.1371(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of concurrent review,* ***(2)*** *an identification of all medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits to which concurrent review applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Concurrent Review [45 CFR 146.137(c)(1)(i)]

Concurrent review is a utilization review service performed by licensed healthcare professionals to review the medical necessity of a patient's care, conducted for M/S and MH/SUD inpatient services, while a member is confined in an inpatient level of care, for dates of service beyond the initial precertification authorization. The purpose is to determine medical necessity and appropriateness of treatment, assess appropriateness of level of care and treatment setting, determine benefits and eligibility, identify the patient's discharge and continuing care plan, and identify and refer potential quality of care and patient safety concerns for additional review. This is considered a clinical review form of concurrent review. Aetna does not conduct other forms of concurrent review.

Inpatient admissions for which precertification is required (that is, almost all M/S and MH/SUD inpatient admissions except for the limited exceptions noted herein) are subject to concurrent review. The following materials describe concurrent review:

1. Plan Documents

Virginia ALIC standard certificate of coverage provides:

Certificate of Coverage – AL VA HCOC 14

Concurrent care claim extension
A concurrent care claim extension occurs when you need us to approve more services than we already have approved. Examples are extending a **hospital stay** or adding a number of visits to a **[provider]**. You must let us know you need this extension [24 hours] before the original approval ends. We will have a decision within [24 hours] for an urgent request. You may receive the decision for a non-urgent request within [15 days].

Concurrent care claim reduction or termination
A concurrent care claim reduction or termination occur when we decide to reduce or stop payment for an already approved course of treatment. We will notify you of such a

determination. You will have enough time to file an appeal. Your coverage for the service or supply will continue until you receive a final appeal decision from us [or an independent review organization if the situation is eligible for external review].

During this continuation period, you are still responsible for your share of the costs, such as **copayments**, **coinsurance** and **deductibles** that apply to the service or supply. If we uphold our decision at the final internal appeal, you will be responsible for all of the expenses for the service or supply received during the continuation period.

Medical necessity[, referral, and, precertification] requirements

Medically necessary, medical necessity

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

[Precertification
You need pre-approval from us for some **covered services**. Pre-approval is also called **precertification**. **Precertification** includes determining that services are not more costly than an alternative service or sequence of services or site of service at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease.

[In-network
Your network **[physician]** or **[PCP]** is responsible for obtaining any necessary **precertification** before you get the care. There is someone available to help your [**physician]** or [**PCP**] 24 hours a day. **Network [providers]** cannot bill you if they fail to ask us for **precertification**. But if your **[physician]** or **[PCP]** requests **precertification** and we deny it, and you still choose to get the care, you will have to pay for it yourself.]

[Out-of-network
[When you go to an **out-of-network [provider]**, you are responsible to get any required **precertification** from us.] [When you go to a **[provider]**, you are responsible to get any required **precertification** from us.] If you don't **precertify**:

- Your benefits may be reduced, or the plan may not pay. See your schedule of benefits for details.
- You will be responsible for the unpaid bills.
- Your additional out-of-pocket expenses will not count toward your **deductible** or **maximum out-of-pocket limit**, if you have any.]

[Timeframes for **precertification** are listed below. For **emergency services**, including an emergency inter-**hospital** transfer of a newborn with a life-threatening condition and for the mother to accompany the newborn, **precertification** is not required, but you should still notify us as shown.

To obtain **precertification**, contact us. You, your **[physician]** or the facility must call us within these timelines:

Type of care	Timeframe
Non-emergency admission	Call at least [14 days] before the date you are scheduled to be admitted
Emergency admission	Call within [48 hours] or as soon as reasonably possible after you have been admitted
Urgent admission	Call before you are scheduled to be admitted
Outpatient non-emergency medical services	Call at least [14 days] before the care is provided, or the treatment or procedure is scheduled

An urgent admission is a **hospital** admission by a **[physician]** due to the onset of or change in an illness, the diagnosis of an illness, or injury.

We will tell you and your **[physician]** in writing of the **precertification** decision, where required by state law. An approval is valid for [30-180 days] as long as you remain enrolled in the plan.

For an inpatient **stay** in a facility, we will tell you, your **[physician]** and the facility about your **precertified** length of **stay**. If your **[physician]** recommends that you stay longer, the extra days will need to be **precertified**. You, your **[physician]**, or the facility will need to call us as soon as reasonably possible, but no later than the final authorized day. We will tell you and your **[physician]** in writing of an approval or denial of the extra days.

If you or your **[provider]** request **precertification** and we don't approve coverage, we will tell you why and explain how you or your **[provider]** may request review of our decision. See the *Complaints, claim decisions [and appeal procedures]* section.]

Types of services that require precertification

Precertification is required for inpatient **stays** and certain outpatient services and supplies.

[Precertification is required for the following types of services and supplies:

[Inpatient –

- [Gender affirming treatment]
- [Gene-based, cellular and other innovative therapies (GCIT)]
- [Obesity (bariatric) **surgery]**
- **Stays** in a hospice facility
- **Stays** in a **hospital**
- **Stays** in a rehabilitation facility
- **Stays** in a **residential treatment facility** for treatment of **mental health disorders** and **substance use disorders**
- **Stays** in a **skilled nursing facility**]

Contact us to get a complete list of the services that require **precertification**. The list may change from time to time.]

Glossary Definition

Medically necessary, medical necessity (mental health or substance use disorder)

A service or product addressing the specific needs of a patient for the purpose of screening, preventing, diagnosing, managing, or treating such disorder, including:

- Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care
- Clinically appropriate in terms of type, frequency, extent, site, and duration
- Not defined primarily for the economic benefit of an insurer or purchaser or for the convenience of the patient, treating physician, or other health care provider.

Generally accepted standards of mental health or substance use disorder care means evidence-based independent standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment. Sources reflecting "generally accepted standards of mental health or substance use disorder care" include:

- Peer-reviewed scientific studies and medical literature
- Consensus guidelines and recommendations of nonprofit health care provider professional associations and specialty societies
- Nationally recognized clinical practice guidelines, including:
  - Patient placement criteria
  - Service intensity assessment instruments
  - Clinical practice guidelines
  - Guidelines and recommendations of federal government agencies
  - Drug labeling approved by the U.S. Food and Drug Administration

Medically necessary, medical necessity (other than mental health or substance use disorder)

Health care services or supplies that prevent, evaluate, diagnose or treat an illness, injury, disease or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with “generally accepted standards of medical practice”
- Clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease
- Not primarily for your convenience, the convenience of your **[physician]**, or other health care **[provider]**
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your illness, injury or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and
- Following the standards set forth in our clinical policies and applying clinical judgment

Important note:
We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Precertification, precertify

Pre-approval that you or your **[provider]** receives from us before you receive certain **covered services**.

2. Provider Contracts

Aetna's template provider contract for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to concurrent review. The same template provider contract is used for both M/S and MH/SUD providers. Specifically, under "Provider obligations," the template contract states: "Provider agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Provider agrees to comply with Company Policies, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria; Provider Manuals; clinical policy bulletins; credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, complaint and appeals, and other policies and procedures (as modified from time to time), that are made available to Provider electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

3. Facility Contracts

In addition, Aetna's template contract for facility providers sets forth the obligations of Aetna's participating facilities with respect to concurrent review. The same template contract is used for both M/S and MH/SUD providers. The contract provides "Facility agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Facility agrees to comply with Company Policies of which Facility knows or reasonably should have known, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria, Provider Manuals, clinical policy bulletins, credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, Institutes of Excellence™, complaint and appeals, and other policies and procedures (as modified from time to time) that are made available to Facility electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

Additionally, under "Facility Obligations," the template contract states:

> Utilization Management. Facility agrees that it shall be subject to utilization management (including prospective, concurrent and retrospective review) and that payment for Facility services may be adjusted or denied for the inefficient delivery of services related to admissions, or length of stay. To facilitate timely and accurate concurrent utilization management, Facility and Company will cooperate as necessary to facilitate on-site and/or concurrent telephonic utilization management at Facility.
>
> Precertification and Referrals. Except when a Member requires emergency services, Facility agrees to comply with any applicable precertification and/or referral requirements under the Member's Plan prior to the provision of Facility services. Facility will utilize the electronic real time HIPAA compliant transactions, including but not limited to, eligibility, precertification and claim status inquiry transactions. Facility agrees to provide notice of all admissions of Members, and of all services for which Company requires notice, upon admission or prior to the provision of such services. For the purpose of pre-admission testing, Facility agrees to directly provide testing or accept test results and examinations performed outside Facility, provided such tests and examinations are: (a) performed by a state licensed laboratory for laboratory tests, and a licensed physician for such other tests and examinations; and (b) performed within a time reasonably proximate to the admission. For those Members who require services under a specialty program, Facility agrees to work with Company in transferring the Member's care to a specialty program Facility, as the case may be.

4. Provider Manual

These requirements are also referenced in Aetna's Provider Manual, applicable to its participating providers. Please see Appendix A for the Provider Manual provisions applicable to concurrent review.

5. Policies and Procedures

The following internal policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address concurrent review.

- **NCS 100: Precertification P&P** – Aetna's policy defining precertification and providing the rules and processes for applying clinical criteria/guidelines to covered benefits for eligible members during the pre-service review process.
- **NCS 200: Concurrent Review and Discharge Planning P&P** – Aetna's policy that establishes the rules for assessing the medical necessity and appropriateness of concurrent care beginning at the onset of services and extending until discharge.
- **NCS 503: Medical Review P&P** – Aetna's policy that explains the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
    - **National Clinical Services (NCS) 503 Medical Review – Virginia**
        - This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
- **NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy** – Aetna's policy outlining the timeliness standards for notifying members/providers of coverage decisions.
    - **National Clinical Services (NCS) 504 Timeliness Standards for Coverage Decisions and Notification Policy - Virginia**
        - This amendment will be used in conjunction with NCS 504 to comply with Virginia requirements.
- **NCS 505: Denial of Coverage Policy and Notification** – Aetna's policy defining and outlining the handling of denial of coverage determinations.
    - **National Clinical Services NCS 505: Denial of Coverage Policy and Notification – Virginia**
        - This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements.
- **NCS 506: Peer-to-Peer Review Policy** – Aetna's policy that describes the process for treating practitioners/clinicians/physicians to discuss a clinical denial with a peer reviewer or behavioral health consultant/psychiatrist/psychologist.
    - **National Clinical Services NCS 506: Peer-to-Peer Review – Virginia**
        - This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.

- **NCS 510: Internal Quality Review Policy** – Aetna policy describing the internal quality review process to assess the compliance with policies and procedures of individuals who support the health plan's medical management programs.

Additionally, Aetna's Care Management Program Description ("**UM Program Description**") encompasses Aetna's utilization management programs for both M/S and MH/SUD services. The UM Program Description defines the scope, goals and objectives, processes, and monitoring of concurrent review and other utilization management programs.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Benefits and Classification

Concurrent review applies to M/S and MH/SUD benefits in the following benefit classifications: **in-network inpatient** and **out-of-network inpatient**.

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **OON IP**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
INN Inpatient All inpatient admissions that extend beyond the initial precertification, including hospital at home, skilled nursing facilities and rehabilitation facilities (except hospice and maternity/newborn stays within the standard length of stay)	**INN Inpatient** All inpatient admissions, including residential treatment facilities, that extend beyond the initial precertification
OON Inpatient All inpatient admissions that extend beyond the initial precertification, including hospital, skilled nursing facilities, rehabilitation facilities and hospice facilities (except maternity/newborn stays within the standard length of stay)	**OON Inpatient** All inpatient admissions, including residential treatment facilities, that extend beyond the initial precertification

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137 (c)(2)]

In accordance with 45 CFR 146.137*(c)(2), this Step 2 is addressed in two Parts:* ***(1)*** *design, and* ***(2)*** *application of concurrent review. Each subpart includes,* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to concurrent review, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137 (c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL.

Factor	Applicable to M/S	Applicable to MH/SUD
Cost management	✓	✓
Clinically appropriate utilization	✓	✓

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standard and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

- **Clinically appropriate utilization** is a **factor** that seeks to ensure that M/S and MH/SUD treatments, procedures, or services are appropriate for the diagnosis, severity of illness, and overall health status of a patient, and that they are provided in accordance with clinically appropriate evidence-based guidelines and practices that are relevant to the condition being treated and that avoids misuse of care.

- In accordance with Virginia's standard certificate of coverage, for M/S services to be medically necessary, they should be "In accordance with generally accepted standards of medical practice, clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease". Medical necessity is comparably described in the COC for MH/SUD services as "Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care and considered clinically appropriate in terms of type, frequency, extent, site, and duration." In general, the following sources contain the evidentiary standards (i.e., clinical treatment guidelines) that are used in the design of this NQTL to support the factor of clinically appropriate utilization. However, for insured plans in some states, applicable state law may require Aetna to apply an alternative standard:
    - MCG Health Care Guidelines
    - National Comprehensive Cancer Network Treatment guidelines
    - American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*
    - Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS)
    - Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII)
    - Aetna Clinical Policy Bulletins

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137 (c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) determining inpatient services subject to precertification, and by extension, concurrent review; and (b) the process of performing concurrent review.

(a) Factors for determining inpatient services subject to precertification and by extension, concurrent review

Factor	Applicable to M/S	Applicable to MH/SUD
Place of service	✓	✓
Federal law	✓	✓

- **Place of service** is a **factor** used to evaluate whether services are subject to a precertification requirement, and by extension, concurrent review, while a member is confined in an inpatient level of care, for dates of service beyond the initial precertification authorization.

Place of service refers to an inpatient admission to a hospital or other healthcare facility (e.g. skilled nursing facility, rehabilitation facility, or residential treatment facility), usually requiring an overnight stay and including room, board, and general nursing care. The **evidentiary standards and sources** upon which this factor is based are:

- All inpatient admissions, except maternity/newborn admissions within the standard length of stay and in-network hospice, for both M/S and MH/SUD conditions, are subject to precertification.
- Place of service is determined based on the bill classification identified on the facility claim submission.

- **Federal law** consists of regulatory and legal requirements concerning precertification requirements for inpatient services. The **evidentiary standards and sources** upon which this factor is based are:
  - Applicable federal laws and regulations, specifically, the federal Newborns' and Mothers' Health Protection Act ("NMHPA") of 1996 which sets minimum length of stay requirements for maternity hospital stays and prohibits insurers from requiring authorization.

(b) Factors for the process of performing concurrent review

Factor	Applicable to M/S	Applicable to MH/SUD
Continued course of treatment	✓	✓
NCQA Guidelines and Standards	✓	✓
Generally accepted standards of medical practice and clinical appropriateness	✓	✓
Applicable state and federal law	✓	✓

- **Continued course of treatment –** Aetna conducts concurrent review for inpatient admissions while a member is confined in an inpatient level of care for dates of service beyond the initial precertification authorization. Aetna will evaluate a member's care as needed, while confined, to ensure the member receives the appropriate level of care at the right time. The **evidentiary standards and sources** upon which this factor is based are:
  - The clinical information from the member's provider care team about the member's condition and progress.

- **National Committee for Quality Assurance (NCQA) Accreditation Standards –** NCQA sets utilization management standards for Health Plan accreditation and Managed

Behavioral Health Organization accreditation. The **evidentiary standards and sources** upon which this factor is based are:

- Timeliness and clinical review standards that Aetna sets to meet NCQA Guidelines and Standards, as implemented through Aetna policies NCS 503: Medical Review P&P and NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P and applicable VA amendments.
- NCQA Health Plan Accreditation and MBHO Utilization Management Standards and Guidelines: Clinical Criteria for UM Decisions, Appropriate Professionals, Timeliness of UM Decisions, and Clinical Information.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in our clinical policies. In general, the following **sources** contain the **evidentiary standards** (i.e., clinical treatment guidelines) utilized by Aetna's clinicians during the concurrent review determination process:

  - Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
  - MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
  - National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
  - American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
  - Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
  - Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

- **Applicable state and federal law** are regulatory and legal requirements concerning the concurrent review process. The **evidentiary standards and sources** upon which this factor is based are:

  - Time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations, as implemented through Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P.

- Timeframes set forth in applicable law for insured plans, that require certain turnaround times for concurrent review decisions in some states. State law or regulation that mandates a more stringent response timeframe supersedes Aetna's national standard, and are acknowledged in state amendments to the corresponding NCS P&Ps.
- Specific medical necessity guidelines set forth in applicable law. Insured plans in a state that requires use of specific medical necessity guidelines are administered in accordance with the state's requirements, and are acknowledged in state amendments to the corresponding NCS P&Ps.
- Other applicable state law requirements pertaining to concurrent review.

<u>Step 3</u>: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45CFR 146.137(c)(3)]

- **Cost management** is a factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management applies equally to all M/S and MH/SUD benefits. Cost management generally underlies Aetna's determination that all M/S and MH/SUD inpatient services require precertification, and by extension, are subject to concurrent review when the stay exceeds the initial precertification authorization.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: With respect to cost management, the evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. Since Aetna's entrance into the insurance and health plan administration business, this factor has been and continues to be a significant operating consideration. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (*see, e.g.,* Form 10-K at page 34 "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of concurrent review, cost management does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Clinically appropriate utilization** is a factor and strategy underlying the design of concurrent review, seeking to ensure the plan covers medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In accordance with Virginia's standard certificate of coverage, medically necessary health care services are those that are clinically appropriate in terms of type, frequency, extent, site, place of service, duration, and considered effective for the member's illness, injury, or disease.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of clinically appropriate utilization applies equally to all M/S and MH/SUD benefits. This design factor aligns to the use of uniform evidentiary standards to assess the clinical appropriateness of a particular service, discussed in more detail below.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** The evidentiary standards considered and relied upon when designing this NQTL are those generally accepted standards of care identified above in Step 2, Part 1 (e.g., MCG, LOCUS, CALOCUS). For M/S benefits, the assessment of whether care is clinically appropriate in the context of concurrent review relies on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. For MH/SUD benefits, clinically appropriate utilization is based on the American Society of Addiction Medicine (ASAM) Criteria: *Addictive, Substance-Related, and Co-*

Occurring Conditions, 3rd Edition, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), and the appropriate Aetna MH/SUD Clinical Policy Bulletins. Please see Aetna's Medical Necessity NQTL Comparative Analysis for a detailed analysis of the factors, evidentiary standards and sources relied upon to adopt Aetna's medical necessity criteria.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of concurrent review, clinically appropriate utilization does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of clinically appropriate utilization, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of cost management and clinically appropriate utilization apply equally and agnostically to both M/S and MH/SUD benefits in the general design of concurrent review. They are interrelated because they collectively seek to ensure that the plan covers only medically necessary, effective, safe, and cost-efficient inpatient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective concurrent review program. Similarly, no one factor is weighted more than another in the design of concurrent review.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in the application of concurrent review for: (a) determining inpatient services subject to precertification, and by extension, concurrent review and (b) the process of performing concurrent review.

(a) Determining inpatient services subject to precertification, and by extension, concurrent review

- **Place of Service** refers to an inpatient admission to a hospital or other healthcare facility (e.g. skilled nursing facility, rehabilitation facility, or residential treatment facility), usually requiring an overnight stay and including room, board, and general nursing care.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Where a service has an inpatient place of service, precertification is required, except for the limited circumstances addressed below. By extension, concurrent review is required for dates of service beyond the initial precertification.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: Place of service is established upon admission to a facility; inpatient admissions as identified by the type of bill code on the claim submission require precertification. The type of bill is a 4-digit code on the UB-04 claim form, as specified by the National Uniform Billing Committee (NUBC). Inpatient claims are identified as:

i. 011x – Inpatient Hospital
ii. 021x – Inpatient Skilled Nursing Facility
iii. 0115 – Hospice Room and Board – Private
iv. 0125 – Hospice Room & Board – Semi-private

Revenue codes are used for MH/SUD inpatient claims. The NUBC also defines and maintains these:

v. 100x – Behavioral Health Accommodations
vi. 1000 – Behavioral Health Accommodations – General
vii. 1001 – Behavioral Health Accommodations – Residential Psychiatric
viii. 1002 – Behavioral Health Accommodations – Residential Chemical Dependency
ix. 1003 – Behavioral Health Accommodations – Supervised Living
x. 1004 – Behavioral Health Accommodations – Halfway House
xi. 1005 – Behavioral Health Accommodations – Group Home

This standard applies equally to M/S and MH/SUD benefits. Claims identified as in-network inpatient hospice, for both M/S and MH/SUD conditions, are not subject to precertification, or by extension, concurrent review.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to inpatient MH/SUD and M/S benefits.

- **Federal law** consists of regulatory and legal requirements concerning precertification requirements for inpatient services that impact concurrent review.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Where applicable federal law would prohibit Aetna from requiring precertification or concurrent review for an inpatient stay, Aetna complies with the applicable legal requirements and does not require precertification or concurrent review.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** In this context, the applicable evidentiary standard is the NMHPA, which sets minimum length of stay requirements for maternity hospital stays. Pursuant to

the NMHPA, a health plan must provide inpatient maternity coverage for a mother and her newborn child for a minimum of 48 hours (2 days) following a normal vaginal delivery, and a minimum of 96 hours (4 days) following a Cesarean section delivery. The health plan cannot require the attending physician to obtain authorization from the plan for prescribing the 48/96-hour minimum stay. If the stay is expected to exceed the 48/96-hour minimum stay, the provider is expected to request prior authorization. If the stay continues beyond the initial precertification period, the stay would then be subject to concurrent review.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to inpatient MH/SUD and M/S benefits.

***Relationship, ordering, and weighting of multiple factors*:** The factors of place of service and applicable federal law are interrelated. However, federal law is weighted, because if there is a maternity/newborn admission claim, prior authorization cannot be required regardless of the place of service. If the stay exceeds the 48/96-hour minimum stay, the stay could be subject to concurrent review. As applied, both factors result in Aetna requiring precertification, and by extension concurrent review, for inpatient admissions for M/S and MH/SUD benefits, except for in-network hospice admissions and where federal law prohibits such a requirement.

(b) Factors for the process of performing concurrent review

For M/S and MH/SUD inpatient services that extend beyond the initial precertification authorization, the below discussion addresses the factors used in the process of conducting concurrent review.

- **Continued course of treatment** is the evaluation of a member's care while confined in an inpatient level of care, for dates of service beyond the initial precertification authorization, to ensure the member receives the appropriate level of care at the right time.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. If a member's inpatient stay extends beyond the initial precertification authorization, concurrent review is required. Updated information about the patient's condition, progress and treatment/discharge plan is obtained from the provider so that clinical staff can make a coverage determination for additional units of care.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that is relied upon when applying this factor is the

clinical information received from the member's provider care team about the member's condition and progress.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of continued course of treatment, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **National Committee for Quality Assurance (NCQA) Accreditation Standards –** NCQA sets utilization management standards for Health Plan accreditation and Managed Behavioral Health Organization accreditation.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna uses NCQA Health Plan and Managed Behavioral Health Organization Utilization Management Standards and Guidelines to adopt policies and procedures for the process of performing concurrent review. These policies are outlined in Step 4, Part 2.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL****:* NCQA Standards and Guidelines require timeliness standards for performing concurrent review. Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy & Procedure establishes the timeliness standards for issuing decisions, and these standards apply equally to M/S and MH/SUD services subject to concurrent review. These standards are outlined in Step 4, Part 2, and are contained in Attachment A of NCS 504. These standards are compliant with NCQA accreditation requirements for precertification, concurrent review and retrospective review. Additionally, the NCQA Standards and Guidelines include requirements pertaining to the clinical criteria used in decision making, the review of relevant medical records, and the involvement of appropriate personnel in decision making. These requirements are implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure and are discussed in detail in Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the NCQA factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical

literature generally recognized by the relevant medical community and the standards set forth in clinical policies.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to determine whether to authorize coverage for additional units of care for M/S and MH/SUD concurrent review requests.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL****:* The **evidentiary standards** relied upon are the following guidelines utilized by Aetna's clinical staff during the concurrent review determination process:

- Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
- MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
- National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff draws upon their training and expertise in applying clinical review criteria/guidelines to determine whether to authorize coverage for M/S and MH/SUD concurrent review requests. This necessarily involves individualized evaluations and determinations for each patient and request for coverage. Please see Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis for additional detail. Additionally, information regarding the nature and timing of the decisions, as well as the designations and qualifications of the clinical staff, is included herein in Step 4, Part 2. When making concurrent review decisions for M/S services, Aetna's clinical staff relies on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. Similarly, when making concurrent review decisions for MH/SUD services, Aetna's clinical staff rely on American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Level of Care Utilization System

for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), and the appropriate Aetna MH/SUD Clinical Policy Bulletins. Staff is required to document the specific clinical guidelines relied upon when making benefit determinations within their documentation notes.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of generally accepted standards of medical practice and clinical appropriateness, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Applicable state and federal law** are regulatory requirements related to the timeframes, use of specific medical necessity criteria, and other requirements applicable to concurrent review.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna complies with applicable state and federal required timeframes for performing concurrent review. Aetna's NCS 504 Policy establishes national standard timeframes which comply with time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations. Aetna's NCS 503 Policy sets forth the medical necessity criteria used in reviewing concurrent requests. State law or regulation that mandates a more stringent response time, requires use of specific medical necessity criteria, or other requirements applicable to concurrent review, supersedes Aetna's national standards.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL****:* The evidentiary standards relied upon are timeframes, specific medical necessity criteria, or other standards that comply with applicable state and federal requirements for concurrent review requests. These standards are reflected in NCS 504 and NCS 503, and the state specific amendments to NCS 504 and NCS 503.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of applicable state and federal law, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering and weighting of multiple factors: The factors listed above apply to distinct aspects of the process of performing concurrent review, including decision-making and the timeliness and medical necessity standards applicable thereto. The factors are interrelated, and all operate together to ensure that Aetna employs an appropriate and effective concurrent review process. As to ordering, updated information about a member's continued course of treatment is

necessary in order to allow for the application of generally accepted standards of medical practice and clinical appropriateness. Additionally, Aetna's national standards discussed above and set forth in NCS policies and procedures are based upon NCQA accreditation requirements and generally accepted standards of medical practice and clinical appropriateness. However, applicable law is weighted more heavily, as applicable law or regulation that mandates a more stringent response time, use of specific medical necessity criteria, or other requirements pertaining to concurrent review, supersedes Aetna's national standards for applicable plans.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, Aetna conducts concurrent review for M/S and MH/SUD inpatient services while a member is confined during an inpatient level of care, for dates of service beyond the initial precertification. Accordingly, concurrent review applies to the following benefit classifications: 1) in-network inpatient and 2) out-of-network inpatient. As noted in Step 2, Part 1, two factors were used in the context of designing concurrent review: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Promotion of cost management and clinically appropriate utilization are general design factors and are a basis and rationale underlying Aetna's policies related to concurrent review requirements for M/S and MH/SUD inpatient services. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, both factors apply equally to both benefit types.

These general design factors are evidenced through general acknowledgement of cost management as a factor in CVS Health public filings noted in Step 3, Part 1, and the specific clinical guidelines identified in Step 2, Part 1, that reflect the clinically appropriate guidelines for both M/S and MH/SUD services. Additionally, Aetna's **UM Program Description** provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." While these materials refer to the general design factors of promotion of cost management and clinically appropriate utilization, there is no written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of concurrent review with respect to M/S and MH/SUD benefits.

These factors apply equally to both benefit types and are not applied incomparably, or more stringently, to MH/SUD benefits in either the in-network inpatient or out-of-network inpatient benefit classifications. Similarly, there are no deviations or variations from these two factors as they apply to the design of concurrent review. As such, Aetna's analysis shows that as written, the processes, strategies, evidentiary standards and other factors used in designing concurrent review with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing concurrent review with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, concurrent review applies to the following benefit classifications: 1) in-network inpatient and 2) out-of-network inpatient. As noted in Step 2, Part 2, different factors are applied in the context of concurrent review for: (a) determining inpatient services subject to precertification, and by extension, concurrent review and (b) the process for performing concurrent review. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying concurrent review to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying the NQTL to M/S benefits.

(a) Determining inpatient services subject to precertification, and by extension, concurrent review

As set forth in Step 2, Part 2, the factors used in the application of concurrent review, to determine inpatient services subject to precertification, and by extension, concurrent review, are

1) place of service and 2) federal law. As written, for both M/S and MH/SUD, concurrent review applies to all in-network and out-of-network inpatient admissions except for the limited instances noted herein. Aetna's analysis of applicable written materials demonstrates that the processes, strategies, evidentiary standards or other factors used to apply concurrent review to MH/SUD benefits are comparable to, and no more stringently applied, than those used to apply concurrent review to M/S benefits.

Per Virginia's standard certificate of coverage, **NCS 100: Precertification Policy**, and its **Provider Manual**, precertification applies to M/S and MH/SUD inpatient admissions. Aetna's Member Precertification List and National Precertification List, discussed at length in Aetna's Precertification Nonquantitative Treatment Limitation Comparative Analysis, memorialize Aetna's determination that all in-network and out-of-network inpatient admissions, whether M/S or MH/SUD, require precertification except for in-network hospice, and maternity and newborn stays that are within the standard length of stay. By extension, per the standard certificate of coverage and Aetna's **NCS 200: Concurrent Review Policy**, concurrent review applies to M/S and MH/SUD inpatient admissions for which precertification is required, while a member is confined in an inpatient level of care for dates of service beyond the initial precertification. Aetna uses the factors 1) place of service and 2) applicable law, which are applied comparably to support the written policies which establish that all inpatient services, except for the exceptions noted, are subject to precertification, and by extension, concurrent review. The place of service for a particular service is determined based on guidance of the National Uniform Billing Committee, which is the governing body for forms and codes used in facility bills. This guidance is used for both M/S and MH/SUD to establish inpatient status such that precertification, and by extension, concurrent review, is required. Aetna applies applicable law in determining which services are/are not subject to precertification and/or concurrent review, which in this instance includes the Newborns' and Mothers' Health Protection Act (NMHPA).

The factors of place of service and federal law are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of concurrent review to MH/SUD inpatient benefits. Regardless of whether the inpatient admission is for an M/S or MH/SUD condition, unless the admission cannot be subject to precertification due to federal law (NMHPA), or the admission is an in-network hospice admission (which would apply whether the hospice admission is for a M/S or a MH/SUD condition), precertification is required. Concurrent review is required for such inpatient stays while a member is confined in an inpatient level of care for dates of service beyond the initial precertification. These considerations apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material used to apply concurrent review and determine which inpatient benefits are subject to precertification, and by extension, concurrent review, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(b) The process of performing concurrent review

As set forth above in Step 2, Part 2, the factors used in application, for the process of performing concurrent review are: 1) continued course of treatment; 2) generally accepted standards of medical practice and clinical appropriateness; 3) NCQA accreditation standards; and 4) applicable state and federal law. These factors support Aetna's written processes for performing concurrent review. These processes are described in detail in the Aetna Utilization Management policies and procedures pertaining to concurrent review. Aetna maintains one set of written UM concurrent review policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to perform concurrent review for M/S and MH/SUD inpatient services:

- NCS 200: Concurrent Review and Discharge Planning Policy & Procedure
- NCS 503: Medical Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure – VA amendment
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy – VA amendment
- NCS 505: Denial of Coverage Policy and Notification
- NCS 505: Denial of Coverage Policy and Notification – VA amendment
- NCS 506: Peer-to-Peer Review Policy
- NCS 506: Peer-to-Peer Review Policy – VA amendment
- NCS 510: Internal Quality Review Policy

Each of these policies is discussed in turn below, demonstrating that they are comparably applied, as written, to MH/SUD and M/S services

NCS 200 defines concurrent review and establishes the rules for assessing the medical necessity and appropriateness of concurrent care beginning at the onset of services and extending until discharge. As noted in the scope of the policy, the policy applies to M/S services and MH/SUD services (called behavioral health). As written in the general section of the policy, the purpose of concurrent review includes:

- Verifying member benefits and identifying potential alternative benefits (e.g., coordination of benefits, Worker's Compensation, Original Medicare as primary carrier);
- Identifying care needs of the member by collecting clinical information from facility staff, practitioners, and providers;
- Coordinating services and supplies;
- Identifying discharge planning needs at the beginning of the inpatient stay;

- Working closely with hospitalists and other facility staff to provide discharge planning assistance throughout the stay;
- Facilitating the delivery of care in the most effective setting taking into account the local health care delivery system, approved guidelines and clinical policy;
- Determining and authorizing the level of coverage appropriate to the member's clinical status and facility services;
- Identifying and referring potential quality of care concerns and patient safety events for additional review; and,
- Identifying potential cases for referral to appropriate specialty programs.

NCS 200 details how concurrent review is administered. In brief, for M/S and MH/SUD services, concurrent review requests and supporting documentation are reviewed using UM decision making criteria that are objective and based on medical evidence to validate the appropriate setting and level of care for the member's clinical condition. The concurrent review procedure, including the UM decision making criteria and its application, follows the procedure detailed in NCS 503, which is listed as a related material in NCS 200. The "as written" processes in NCS 200 to determine whether to approve or deny concurrent review requests are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. While NCS 200 refers to separate UM units that handle M/S and MH/SUD requests, the processes followed by those units are comparable and no more stringently applied to MH/SUD.

NCS 503 establishes the process of medical review and establish the written clinical criteria/guidelines used by Aetna's clinicians in making medical necessity determinations. This policy applies equally to M/S and MH/SUD services. For both M/S and MH/SUD services, the guiding strategy behind concurrent review relies upon the clinical reviewers' exercise of their clinical judgment, guided by clinical criteria, to determine whether to authorize coverage for additional units of care. While NCS 503 sets forth separate written guidelines that apply to M/S and MH/SUD services, all services are subject to appropriate guidelines based on industry standards and generally accepted standards of medical practice and clinical appropriateness. NCS 503 otherwise does not differentiate between M/S and MH/SUD services. The relevant specific written guidelines referred to in NCS 503 are:

- **LOCUS and CALOCUS/CASII** (MH/SUD) – Aetna uses the most current versions of LOCUS and CALOCUS/CASII, which are recognized nationally as a generally accepted standard of care tool, to guide clinicians in making medically necessary level of care determinations for mental health services. The Level of Care Utilization System (LOCUS) assessment was developed by the American Association of Community Psychiatrists (AACP) in 1996 to help determine the mental health care resource intensity needs of adults. CALOCUS was developed was developed by the American Association of Community Psychiatrists in collaboration with the American Association of Child and Adolescent Psychiatry to help determine the mental health care resource intensity needs of children and adolescents.

- **ASAM** (MH/SUD) – Aetna uses the most current criteria published by the American Society of Addiction Medicine (ASAM) to guide clinicians in evaluating the medical necessity of levels and types of care for substance use disorders. ASAM criteria are generally accepted, national standards for SUD treatment decisions and are recognized as such by many courts and regulators.

- **MCG Health Care Guidelines** (M/S) – Aetna uses the most current evidence-based Care Guidelines published by MCG Health to guide clinicians in making medically necessary level of care determinations for M/S services.
- **Aetna Clinical Policy Bulletins (CPBs)** (M/S and MH/SUD) – Aetna CPBs describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's medical necessity decisions regarding specific M/S and MH/SUD services.

- **NCCN Clinical Practice Guidelines in Oncology** (M/S) – Aetna uses the most current clinical practice guidelines published by the National Comprehensive Cancer Network (NCCN) to make medical necessity determinations in oncology clinical reviews. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are comprised of recommendations for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines currently apply to more than 97% of cancers affecting patients in the United States. The NCCN Guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management.

- **Section 38.2-3418.17 of the Code of Virgina –** Aetna uses the VA specific legislation to establish procedures around handling prior-authorization requests for individuals receiving treatment for an autism spectrum disorder and prior authorization for drugs prescribed for the treatment of a mental disorder listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

Regarding application of state law, state amendments to NCS 503 reflect state law requirements applicable to precertification, and by extension, concurrent review, including limitations on medical review requirements and/or the use of alternative M/S and MH/SUD medical necessity guidelines as required by state law where applicable. Medical necessity guidelines do not replace professional judgment exercised by properly trained, licensed, and experienced clinicians and professionals who evaluate the provision of services in accordance with accepted standards of care. As explained in NCS 503, individual M/S and MH/SUD medical necessity determinations are afforded independent clinical consideration based on the member's presentation. As listed in NCS 503, staff considers the individual needs of the member when utilizing guidelines, including, but not limited to age, co-morbidities, complications, progress of

treatment, need for skilled care, psychosocial situation, risk related to ethnicity or genetic factors and home environment, when applicable. Staff additionally considers the following characteristics of the local health care delivery system during the coverage determination process: the ability of the provider to meet the member's cultural and language needs, as appropriate; the availability of highly specialized services, such as detoxification facilities; the availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and, the ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition. NCS 503 further notes that approval decisions may be automated when appropriate. Automation uses clinical information submitted by the provider and compares it to Aetna's clinical policies to render an approval decision, based on individualized clinical considerations, using the medical necessity guidelines outlined in NCS 503. For both M/S and MH/SUD medical necessity reviews, all adverse decisions are made by medical directors, never by automation or clinical staff who are not medical directors, as required by NCS 505: National Clinical Services Denial of Coverage Policy, discussed below. Thus, the "as written" material contained in NCS 503 pertaining to the medical review process is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 504 establishes the timeliness standards for concurrent review determinations and notifications that apply equally to M/S and MH/SUD services. All concurrent reviews for M/S and MH/SUD inpatient services are considered urgent and are handled in accordance with the instructions contained in NCS 504 for urgent concurrent review coverage requests. Attachment A to NCS 504 sets out timeliness standards for concurrent review decisions and notifications, separated into standards for initial concurrent review requests, and subsequent concurrent review requests for extension for additional days/services. These timeliness standards apply equally to M/S and MH/SUD inpatient concurrent review.

Urgent concurrent review requests (initial request)

Pursuant to NCS 504, initial determinations for urgent concurrent review requests that include all necessary clinical information, are made within 1 calendar day of the request. Aetna will notify the requester of the determination (approval and denial) verbally within 1 calendar day of the receipt of the request. For approvals, a written notification will be sent upon request. For denials, a written notification will be sent within 1 calendar day of the receipt of the request. The 1 calendar day determination timeframe is an NCQA requirement. If additional information is required to make a determination, Aetna will initiate the request for additional information within 24 hours of the receipt of the request. These timelines apply equally to M/S and MH/SUD and are detailed in NCS Policy 504: Timeliness Standards for Coverage Decisions and Notification Policy (Attachment A).

Urgent concurrent review requests (extension requests for additional days/services)

These timelines apply equally to M/S and MH/SUD and are detailed in NCS Policy 504, Timeliness Standards for Coverage Decisions and Notification Policy (Attachment A).

- Pursuant to NCS 504, for extension requests for additional days/services that are made 24 hours or less prior to the end of the previously reviewed period, the following timeliness standards apply: For requests that include all necessary clinical information, Aetna will notify requester of the determination (approval and denial) within 72 hours of the receipt of the request. For approvals, a written notification will be sent upon request. For denials, if direct telephonic notification is provided within 72 hours from the receipt of the request, then the written notification must be sent within 3 calendar days of the telephonic notice.
- If additional information is required to make a determination, Aetna will initiate the request for additional information within 24 hours of the receipt of the request. These timelines apply equally to M/S and MH/SUD and are detailed in NCS Policy 504, Timeliness Standards for Coverage Decisions and Notification Policy (Attachment A).
- For extension requests for additional days/services that are made more than 24 hours prior to the end of the previously reviewed period, Aetna will notify requester of the determination (approval and denial) within 24 hours of the receipt of the request. For approvals, a written notification will be sent upon request. For denials, if direct telephonic notification is provided within 72 hours from the receipt of the request, then the written notification must be sent within 3 calendar days of the telephonic notice.

The timeframes and procedures set forth in NCS 504 are equally applicable to concurrent reviews for M/S and MH/SUD inpatient services and are based on the factors of NCQA accreditation standards and applicable state and federal law. NCS 504 notes that the Aetna standard timeframes set forth above are in compliance with applicable accreditation requirements and federal law, and that state law or regulation that mandates a more stringent time supersedes the national standard. The "as written" processes in NCS 504 dictating timeliness standards for conducting concurrent review requests are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services.

Additionally, **NCS 505** defines and outlines the handling of denial of coverage determinations, including responsibility for issuing clinical and administrative denial decisions, documentation requirements for denial decisions, and notification requirements for these coverage decisions. As written, this policy applies equally to M/S and MH/SUD, which specifies that only M/S and MH/SUD medical directors can deny clinical coverage decisions. Because the processes are the same, the "as written" material contained in NCS 505 pertaining to the handling of coverage determination denials is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 506 outlines the peer-to-peer review process through which a treating practitioner, a clinician on behalf of the treating practitioner (e.g., genetic counselor for BRCA precertification

requests) or a physician on behalf of a facility (for concurrent review denials) may request a discussion with a peer reviewer (licensed health plan physician medical director) or behavioral health consultant psychiatrist/psychologist/board certified behavior analyst-doctoral (BCBA-D), to discuss a clinical denial of coverage determination. Peer-to-peer is not an additional level of review or an appeal. It is a focused discussion between the provider representative and the peer reviewer. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D considers all available information when conducting a peer-to-peer review. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D reviews the applicable clinical criteria/guidelines in NCS 503, the clinical information that is present before and during the peer-to-peer discussion and uses clinical judgment to make a decision. For M/S, peer-to-peer reviews are conducted after a denial determination, upon request. For MH/SUD services, when clinically appropriate, peer-to-peer reviews are offered and conducted prior to the issuance of the initial coverage determination, in addition to peer-to-peer reviews that are available after a denial determination. As written, the process for peer-to-peer review is largely the same for M/S and MH/SUD, except that for MH/SUD services, Aetna may offer a peer-to-peer review before a determination has been issued, in addition to the peer-to-peer review that is available post-determination. Based upon the foregoing, the written material contained in NCS 506 pertaining to peer-to-peer review is comparably applied to MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

Finally, **NCS 510** describes Aetna's Internal Quality Review and Inter-Rater Reliability assessments. As written, the IQR/IRR process provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. Through inter-rater reliability (IRR) assessments, both M/S and MH/SUD medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria, and corrective actions are taken if the results do not meet certain metrics, which are the same for MH/SUD and M/S services. NCS 510 applies equally to M/S and MH/SUD services, and the processes set forth therein are the same for M/S and MH/SUD services. The "as written" processes in NCS 510, for evaluation of medical director and utilization management clinician accuracy and consistency, are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. The IRR results for both Behavioral Health and Medical clinicians are discussed in Step 5, and show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

The factors of 1) continued course of treatment; 2) generally accepted standards of medical practice and clinical appropriateness; 3) NCQA accreditation standards; and 4) applicable state and federal law, are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently, as written, to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the process of performing concurrent review for MH/SUD services. The written policies discussed above support these factors and are equally applicable to performing concurrent reviews for M/S and MH/SUD inpatient services. The

factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Accordingly, Aetna's analysis of the "as written" material used to perform concurrent reviews shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services than to M/S services.

Aetna provides members with appeal rights when an adverse benefit determination is issued. When Aetna issues a denial of services or a reduction in coverage due to an EIU determination or blanket exclusion, that determination is considered an adverse benefit determination. Members have the right to request a review of that determination through the appeal process and may initiate an appeal by contacting Aetna.

Appeal rights and procedures are described in the COC under the section titled "Appeal of an Adverse Benefit Determination." The COC outlines the appeal process, including applicable timeframes, who may request an appeal on behalf of the member, how appeals are assigned and reviewed, and the options available if the member is not satisfied with the appeal decision. Aetna does not maintain separate appeal processes for MH/SUD services and M/S services; the same appeal procedures apply to both. In addition, once the internal appeal process has been exhausted, members may have the right to request an external review, as described in the COC. The COC also explains the circumstances under which external review may be available and the procedures for requesting it. The appeal and external review rights available to members are applied consistently for MH/SUD and M/S services and are not more stringent for MH/SUD services than for M/S services.

Summary

In sum, Aetna's analysis demonstrates that as written, the processes, strategies, evidentiary standards and other factors used in applying concurrent review to MH/SUD benefits are comparable to and are applied no more stringently than the processes, strategies, evidentiary standards and other factors used in applying concurrent review to M/S benefits in the applicable benefit classifications.

<u>Step 5</u>: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

**The quantitative data presented in this analysis is based on Aetna Life Insurance Company (ALIC) business, which represents approximately 74% of the total Virginia business. The NQTL processes, strategies, evidentiary standards, and other factors described herein are applied consistently across the relevant Virginia business. As a result, Aetna believes the ALIC data is representative of the operational application of the NQTL and provides a reliable basis for assessing compliance with MHPAEA's comparative analysis requirements and for supporting the findings and conclusions presented in this report.*

As noted in Step 1, Part 2, concurrent review applies to the following benefit classifications: 1) in-network inpatient and 2) out-of-network inpatient. As noted in Step 2, Part 2, different factors are applied in the context of concurrent review for: (a) determining inpatient services subject to precertification, and by extension, concurrent review and (b) the process for performing concurrent review. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying concurrent review to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying concurrent review with respect to M/S benefits.

(a) Determining inpatient services subject to precertification, and by extension, concurrent review

In operation, precertification is required for all inpatient admissions for both M/S and MH/SUD services, except as noted above with respect to maternity/newborn stays and in-network hospice, which are equally applicable to M/S and MH/SUD conditions. By extension, concurrent review is required, for such inpatient stays, while a member is confined in an inpatient level of care for dates of service beyond the initial precertification. Thus, in operation, the factors, processes, strategies and evidentiary standards used to determine which MH/SUD inpatient services are subject to concurrent review are comparable to, and are applied no more stringently than, the factors, processes, strategies and evidentiary standards with respect to M/S services.

(b) The process of performing concurrent review

Aetna monitors the denial rates for M/S and MH/SUD concurrent review requests as one measure that can evaluate whether concurrent review is applied comparably, and not more stringently, to MH/SUD services compared to M/S services. Evaluation of this data for M/S and MH/SUD services can provide a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the precertification process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits.

The data below are retrieved from Aetna's utilization management system and reflects the total number of decisions and the total number of decisions that were denied. The data is further broken down into administrative denials and medical necessity denials. Administrative denials are based on a failure to meet plan administrative requirements, including the member's lack of eligibility, missing information required to complete the review, the benefits for the requested services are excluded under the member's plan, or the benefits have been exhausted under the member's plan. Medical necessity denials are denials for which the requested service did not meet the medically necessary criteria used by clinicians during the concurrent review process.

Concurrent Review Decisions	**In-network Inpatient M/S**	**In-network Inpatient MH/SUD**	**Out-of-network Inpatient M/S**	**Out-of-network Inpatient MH/SUD**
Total Decisions	1203	129	13	24
Denied Decisions	294	15	2	9
Overall Percent Denied	**24.44%**	**11.63%**	**15.38%**	**37.5%**
Total Administrative Denials	163	8	1	7
Percent Denied - Administrative	**13.55%**	**6.20%**	**7.69%**	**29.17%**
Total Medical Necessity Denials	131	7	1	2
Percent Denied – Medical Necessity	**10.89%**	**5.43%**	**7.69%**	**8.33%**

As demonstrated in Step 5, with respect to the concurrent review process, an in-operation review of concurrent review determinations for VA ALIC business indicates that the concurrent review process is administered comparably for MH/SUD and M/S services and is not applied more stringently to MH/SUD services. For in-network inpatient services, the overall concurrent review denial rate was 11.63% for MH/SUD services (15 denials out of 129 determinations), compared to 24.44% for M/S services (294 denials out of 1,203 determinations). In addition, the administrative denial rate for MH/SUD services was 6.20%, compared to 13.55% for M/S services, and the medical necessity denial rate for MH/SUD services was 5.43%, compared to 10.89% for M/S services. These results demonstrate that, in operation, concurrent review denials for in-network inpatient MH/SUD services occurred less frequently than for comparable M/S services.

For out-of-network inpatient services, the overall denial rate was 37.50% for MH/SUD services (9 denials out of 24 determinations), compared to 15.38% for M/S services (2 denials out of 13 determinations). The administrative denial rate was 29.17% for MH/SUD services and 7.69% for M/S services, while the medical necessity denial rates were generally comparable at 8.33% and 7.69%, respectively, a difference of less than one percent. These results are based on a limited number of determinations, particularly within the out-of-network inpatient population, and therefore have limited statistical credibility and are not necessarily representative of broader utilization and review patterns.

Accordingly, the available concurrent review data do not indicate that the factors, evidentiary standards, or processes used to conduct concurrent review are applied more stringently to MH/SUD services than to comparable M/S services. Rather, the data reflect lower denial rates for MH/SUD services in the in-network inpatient classification and limited out-of-network inpatient experience that does not support a conclusion that concurrent review operates more restrictively for MH/SUD benefits. Based on the data evaluated, Aetna may conclude that the concurrent review NQTL is applied comparably, and not more stringently, to MH/SUD services than to analogous M/S services.

Additionally, the IRR process described in NCS 510: Internal Quality Review Policy & Procedure provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. In that process, medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria. Corrective actions are taken if the results do not meet certain individual and business unit metrics, which are the same for M/S and MH/SUD. The IRR results for both Behavioral Health and Medical clinicians and medical directors show that the audits were performed as required and the overall goals met. Overall, the final score for M/S utilization reviews was 98%. For MH/SUD, the final score was 100%. These IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

Summary

In sum, review of the data addressed herein provides a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the concurrent review process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits. Based on the in-operation data and reviews discussed above, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying concurrent review to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying concurrent review with respect to M/S benefits in the applicable benefit classifications.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of §146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, concurrent review is a utilization review service performed by licensed healthcare professionals to review the medical necessity of a patient's care, conducted for M/S and MH/SUD inpatient services, while a member is confined in an inpatient level of care, for dates of service beyond the initial precertification authorization. The purpose is to determine medical necessity and appropriateness of treatment, assess appropriateness of level of care and treatment setting, determine benefits and eligibility, identify the patient's discharge and continuing care plan, and identify and refer potential quality of care and patient safety concerns for additional review. As further demonstrated in Step 1, concurrent review applies to the following benefit classifications: 1) in-network inpatient and 2) out-of-network inpatient. Concurrent review applies to all M/S and MH/SUD inpatient services, except for the limited exceptions discussed above which are equally applicable to both M/S and MH/SUD services, while a member is confined to an inpatient level of care for dates of service beyond the initial precertification authorization.

Step 2 identified the factors that are used to determine: 1) the inpatient services subject to precertification, and by extension, concurrent review, and 2) the process of performing concurrent review. Step 3 explained the evidentiary standards and sources for those factors, and how they are used in the design and application of concurrent review. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD services. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD services subject to concurrent review and concluded that there are no written differences in that application that results in any MH/SUD

services being treated more stringently than, or incomparably to, M/S services. Finally, Step 5 demonstrated that, in operation, M/S and MH/SUD services are subject to concurrent review in a comparable manner, and the MH/SUD services to which concurrent review applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S services.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors, evidentiary standards, and sources, and the same National Clinical Services Policies and Procedures, to determine the inpatient services that are subject to concurrent review, and to administer concurrent review for M/S and MH/SUD benefits. Two factors are used in the context of designing concurrent review: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Promotion of cost management and clinically appropriate utilization are general design factors and are a basis and rationale underlying Aetna's policies related to concurrent review requirements for M/S and MH/SUD inpatient services. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, both factors apply equally to both benefit types.

The factors used in the application of concurrent review, to determine inpatient services subject to precertification, and by extension, concurrent review, are 1) place of service and 2) federal law. Both in writing, and in operation, concurrent review applies to all in-network and out-of-network inpatient admissions except for the limited instances noted herein. The factors used in application, for the process of performing concurrent review are: 1) continued course of treatment; 2) generally accepted standards of medical practice and clinical appropriateness; 3) NCQA accreditation standards; and 4) applicable state and federal law. These factors support Aetna's written processes for performing concurrent review. Aetna maintains one set of written NCS utilization management concurrent review policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to perform concurrent review for M/S and MH/SUD inpatient services. The factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. Both in writing, and in operation, the same processes apply to conduct concurrent review for both M/S and MH/SUD benefits.

As demonstrated in Step 5, in operation, concurrent review is required and administered in a comparable manner for both M/S and MH/SUD inpatient services. As further demonstrated in Step 5, an in-operation review of the in-network and out-of-network inpatient concurrent review determinations conducted for VA ALIC business does not indicate that concurrent review is applied more stringently to MH/SUD services than to comparable M/S services. For in-network inpatient services, the overall denial rate for MH/SUD services was 11.63%, compared to 24.44% for M/S services. In addition, both the administrative denial rate (6.20% for MH/SUD services compared

to 13.55% for M/S services) and the medical necessity denial rate (5.43% for MH/SUD services compared to 10.89% for M/S services) were lower for MH/SUD services than for M/S services.

For out-of-network inpatient services, the overall denial rate was 37.50% for MH/SUD services, compared to 15.38% for M/S services. . The observed administrative denial rates (29.17% for MH/SUD services compared to 7.69% for M/S services) and medical necessity denial rates (8.33% for MH/SUD services compared to 7.69% for M/S services) were based on a limited number of determinations, including only 24 MH/SUD determinations and 13 M/S determinations.

Accordingly, the available operational data do not support a conclusion that concurrent review is administered more restrictively for MH/SUD services than for comparable M/S services. Rather, the data demonstrate lower overall, administrative, and medical necessity denial rates for MH/SUD services in the in-network inpatient classification, while the out-of-network inpatient results are based on limited data and do not indicate a systematic disparity in the application of concurrent review. Based on the data evaluated, Aetna may conclude that the factors, evidentiary standards, and sources used in the administration of the concurrent review NQTL are comparable for MH/SUD and M/S services and are not applied more stringently to MH/SUD benefits.

The IRR reports show that both Medical and Behavioral Health medical directors and clinicians are performing utilization management reviews accurately and consistently overall. The final overall score for M/S utilization reviews was 98%. For MH/SUD, the final overall score was 100%.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply concurrent review to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying concurrent review to M/S benefits across the applicable benefit classifications. The factors, evidentiary standards and sources used to determine what services are subject to concurrent review, and to conduct concurrent review, are designed and applied in a comparable, and not more stringent manner, for MH/SUD benefits in all applicable benefit classifications both in writing and in operation. Taken together with the favorable outcomes for MH/SUD at the book of business level, the concurrent review NQTL is designed and applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Behavioral Health Medical Director, Quality and Mental Health Parity, Medical Doctor board certified in Psychiatry

	• Lead Director, Clinical Review Program Management • Sr. Manager, Clinical Health Services, LCSW

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Nonquantitative Treatment Limitation Comparative Analysis:

RETROSPECTIVE REVIEW

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of retrospective review, and* ***(2)*** *an identification of all medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits to which retrospective review applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong*.

Step 1, Part 1. Identification of the NQTL: Retrospective Review [45 CFR 146.137(c)(1)(i)]

Retrospective review is a utilization review service performed by licensed healthcare professionals to determine coverage after an inpatient discharge or the provision of a procedure/service. The intent of the review is to determine medical necessity, appropriateness of treatment, and benefits and eligibility. For purposes of this analysis, Aetna's Retrospective Review NQTL includes all post-service utilization review activities conducted following the rendering of services, without distinction based on whether the review occurs before or after claim payment. Aetna applies a common retrospective review framework and does not utilize separate factors, evidentiary standards, clinical review criteria, or methodologies based solely on claim payment status. Therefore, Aetna evaluates pre-payment and post-payment retrospective review within a single Retrospective Review NQTL analysis. Fraud, Waste, and Abuse ("FWA") functions are addressed in a separate FWA NQTL analysis.

Aetna conducts retrospective review of services for which precertification was required, but was not obtained, for M/S and MH/SUD inpatient and outpatient out-of-network benefits ("OON benefits") and in-network benefits ("INN benefits"). For OON benefits, Aetna performs retrospective review on all M/S and MH/SUD OON inpatient services and outpatient all-other services for which precertification was required under the terms of the member's plan, but for which precertification was not obtained. For INN benefits, because in-network providers are contractually required and expected to comply with applicable precertification and timely notification requirements, Aetna only performs retrospective review for M/S and MH/SUD INN inpatient services and outpatient–all other services for which precertification was required, but was not obtained, in limited circumstances which are: 1) for INN M/S and MH/SUD inpatient services under circumstances discussed herein; 2) when provider precertification and/or timely notification requirements are waived based on federal or state law requirements and/or an applicable disaster declaration; 3) when required by Aetna's contract with a participating provider; or 4) when there is a valid reason for failure to precertify or give timely notice (e.g., member was unable to provide

insurance information at the time). For emergency services, Aetna performs retrospective review where the M/S and MH/SUD diagnosis codes submitted on an emergency department claim signify a condition that potentially was not an emergency as defined pursuant to the federal "prudent layperson" standard. Aetna maintains a Non-Emergent ER Diagnosis Codes List which consists of a list of M/S and MH/SUD diagnosis codes that would not standardly be appropriate for an emergency room setting and signify that a condition may not have been an emergency under the prudent layperson standard. If all diagnosis codes on a submitted emergency department claim are listed on Aetna's Non-Emergent ER Diagnosis Codes List, Aetna conducts retrospective review based on the medical records to determine whether the treatment was in fact for an emergency condition. The following materials describe retrospective review:

1. Plan Documents

Virginia's standard certificate of coverage provides:

Certificate of Coverage – AL HCOC 14

Medical necessity[, referral, and, precertification] requirements

Medically necessary, medical necessity

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

[Precertification
You need pre-approval from us for some **covered services**. Pre-approval is also called **precertification**. **Precertification** includes determining that services are not more costly than an alternative service or sequence of services or site of service at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury, or disease.

[In-network
Your network **[physician]** or **[PCP]** is responsible for obtaining any necessary **precertification** before you get the care. There is someone available to help your [**physician]** or [**PCP**] 24 hours a day. **Network [providers]** cannot bill you if they fail to ask us for **precertification**. But if your **[physician]** or **[PCP]** requests **precertification** and we deny it, and you still choose to get the care, you will have to pay for it yourself.]

[Out-of-network
[When you go to an **out-of-network [provider]**, you are responsible to get any required **precertification** from us.] [When you go to a **[provider]**, you are responsible to get any required **precertification** from us.] If you don't **precertify**:

- Your benefits may be reduced, or the plan may not pay. See your schedule of benefits for details.
- You will be responsible for the unpaid bills.

Your additional out-of-pocket expenses will not count toward your **deductible** or **maximum out-of-pocket limit**, if you have any.]

[Timeframes for **precertification** are listed below. For **emergency services**, including an emergency inter-**hospital** transfer of a newborn with a life-threatening condition and for the mother to accompany the newborn, **precertification** is not required, but you should still notify us as shown.

To obtain **precertification**, contact us. You, your **[physician]** or the facility must call us within these timelines:

Type of care	Timeframe
Non-emergency admission	Call at least [14 days] before the date you are scheduled to be admitted
Emergency admission	Call within [48 hours] or as soon as reasonably possible after you have been admitted
Urgent admission	Call before you are scheduled to be admitted
Outpatient non-emergency medical services	Call at least [14 days] before the care is provided, or the treatment or procedure is scheduled

An urgent admission is a **hospital** admission by a **[physician]** due to the onset of or change in an illness, the diagnosis of an illness, or injury.

We will tell you and your **[physician]** in writing of the **precertification** decision, where required by state law. An approval is valid for [30-180 days] as long as you remain enrolled in the plan.

For an inpatient **stay** in a facility, we will tell you, your **[physician]** and the facility about your **precertified** length of **stay**. If your **[physician]** recommends that you stay longer, the extra days will need to be **precertified**. You, your **[physician]**, or the facility will need to call us as soon as reasonably possible, but no later than the final authorized day. We will tell you and your **[physician]** in writing of an approval or denial of the extra days.

If you or your **[provider]** request **precertification** and we don't approve coverage, we will tell you why and explain how you or your **[provider]** may request review of our decision. See the *Complaints, claim decisions [and appeal procedures]* section.]

Types of services that require precertification

Precertification is required for inpatient **stays** and certain outpatient services and supplies.

[Precertification is required for the following types of services and supplies:

[Inpatient –

- [Gender affirming treatment]

- [Gene-based, cellular and other innovative therapies (GCIT)]
- [Obesity (bariatric) **surgery]**
- **Stays** in a hospice facility
- **Stays** in a **hospital**
- **Stays** in a rehabilitation facility
- **Stays** in a **residential treatment facility** for treatment of **mental health disorders** and **substance related disorders**
- **Stays** in a **skilled nursing facility**]

[Outpatient –

- [Applied behavior analysis]
- [ART services]
- Complex imaging
- Cosmetic and reconstructive **surgery**
- [Gender affirming treatment]
- [Gene-based, cellular and other innovative therapies (GCIT)]
- [Home health care]
- Hospice care
- Injectables, (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications)
- Kidney dialysis
- Knee **surgery**
- [Limited infertility services]
- Non-emergency transportation by airplane
- [Obesity (bariatric) **surgery]**
- Outpatient back **surgery** not performed in a **[physician's]** office
- Partial hospitalization treatment – **mental health disorders** and **substance use disorders** treatment
- [Private duty nursing services]
- Sleep studies
- Transcranial magnetic stimulation (TMS)
- Wrist **surgery**]

Contact us to get a complete list of the services that require **precertification**. The list may change from time to time.]

Sometimes you or your **[provider]** may want us to review a service that doesn't require **precertification** before you get care. This is called a predetermination, and it is different from **precertification**. Predetermination means that you or your **[provider]** requests the pre-service clinical review of a service that does not require **precertification**.

[Emergency services
When you experience an **emergency medical condition**, you should go to the nearest emergency room. You can also dial 911 or your local emergency response service for medical and ambulance help.

Covered services include only outpatient services to evaluate and stabilize an **emergency medical condition** in a **hospital** emergency room or an independent freestanding emergency department, including:

- Diagnostic x-ray
- Lab services
- Medical supplies
- Advanced diagnostic imaging, such as MRIs and CAT scans

Emergency services for behavioral health conditions may be obtained from a facility and staff credentialed to provide behavioral health crisis services. These services include the following when they are within the capabilities of the staff and facilities available at the behavioral health crisis **provider**:

- A behavioral health assessment, including ancillary services routinely available to evaluate an **emergency medical condition**, and
- Further examination and treatment as are required so that your condition does not deteriorate

[You can get **emergency services** from network or **out-of-network [providers]**.]

Your coverage for **emergency services** will continue until the following conditions are met:

- You are evaluated and your condition is stabilized
- Post-stabilization: your attending **[physician]** determines that you are medically able to travel or be transported, by non-medical or non-emergency transportation, to another **[provider]** or facility located within a reasonable travel distance, taking into account your medical condition

[If your **[physician]** decides you need to stay in the **hospital** (emergency admission) or receive follow-up care, these are not **emergency services**. Different benefits and requirements apply. See the [*How your plan works –Medical necessity[and, precertification] requirements*] [*How your plan works – Medical necessity[, referral, and, precertification] requirements*] section and the *Coverage and exclusions* section that fits your situation (for example, *Hospital care* or *[Physician] services*). [You can also contact us or your network **[physician]** [or **[primary care provider (PCP)]**].] [You can also contact us or your **[physician]**.]]

Benefit payments and claims

A claim is a request for payment that you or your health care **[provider]** submits to us when you want or get **covered services**. There are different types of claims. You or your **[provider]** may contact us at various times, to make a claim, to request approval, or payment, for your benefits. This can be before you receive your benefit, while you are receiving benefits and after you have received the benefit.

It is important that you carefully read the previous sections within *How your plan works*. When a claim comes in, we review it, make a decision and tell you how you and we will split the expense. The amount of time we have to tell you about our decision on a claim depends on the type of claim.

Claim type and timeframes

Post-service claim

A post-service claim is a claim that involves health care services you have already received. We will make a decision within [30 days].

Glossary Definition

Precertification, precertify
Pre-approval that you or your **[provider]** receives from us before you receive certain **covered services**.

Emergency medical condition
Regardless of the final diagnosis rendered to you, a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, that:

- Needs immediate medical care
- Leads a prudent layperson with average knowledge of health and medicine

to reasonably believe that, without immediate medical care, it could result in:

- Danger to physical or mental health
- Danger of serious impairment to a bodily function
- Serious dysfunction to any bodily part or organ, or
- In the case of a pregnant woman, danger to the health of an unborn baby

Emergency services
A medical screening examination, including ancillary services, given in a **hospital's** emergency room or an independent freestanding emergency department to evaluate an **emergency medical condition**. This includes any further medical examination of and treatment to stabilize the patient. **Emergency services** also include behavioral health assessments and routine ancillary services by a behavioral health crisis service provider to evaluate, treat, or prevent a patient's condition from deteriorating.

An independent freestanding emergency department means a health care facility that is geographically separate, distinct, and licensed separately from a **hospital** and provides **emergency services**.

Stabilize means providing treatment to assure the condition will not get worse as a result of, or during, the transfer of the individual from a facility. For a pregnant woman, stabilize also means that the woman has delivered, including the placenta.

2. Provider Contracts

Aetna's template provider contract for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to retrospective review. The same template provider contract is used for both M/S and MH/SUD providers.

Specifically, under "Provider obligations," the template contract states:

> General Obligations. Provider agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan.
>
> Compliance with Company Policies. Provider agrees to comply with Company Policies, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time.

> Member Billing. Provider agrees that Members will not be billed or charged any amount for Covered Services, except for applicable copayments, coinsurance and deductible amounts. If services are not reimbursed because of Provider's failure to comply with its obligations under this Agreement (e.g., for late submission of claims), Members may not be billed for those services. A Member may be billed for services that are not Covered Services under the Member's Plan (including for services that are not considered "medically necessary" under a Plan) as long as the Member is informed that those services are not covered and has agreed, in advance, to pay for the services. This section will survive the termination of this Agreement.

Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria; Provider Manuals; clinical policy bulletins; credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, complaint and appeals, and other policies and procedures (as modified from time to time), that are made available to Provider electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

3. Facility Contracts

In addition, Aetna's template facility contract sets forth the obligations of Aetna's participating facilities with respect to retrospective review. The same template provider contract is used for both M/S and MH/SUD providers. The contract provides "Facility agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Facility agrees to comply with Company Policies of which Facility knows or reasonably should have known, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria, Provider Manuals, clinical policy bulletins, credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, Institutes of Excellence™, complaint and appeals, and other policies and procedures (as modified from time to time) that are made available to Facility electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

Additionally, under "Facility Obligations," the template contract states:

> Member Billing. Facility agrees that Members will not be billed or charged any amount for Covered Services, except for applicable copayments, coinsurance and deductible amounts. If services are not reimbursed because of Facility's failure to comply with its obligations under this Agreement (e.g., for late submission of claims), Members may not be billed for those services. A Member may be billed for services that are not Covered Services under the Member's Plan (including for services that are not considered

"medically necessary" under a Plan) as long as the Member is informed that those services are not covered and has agreed, in advance, to pay for the services. This section will survive the termination of this Agreement.

Utilization Management. Facility agrees that it shall be subject to utilization management (including prospective, concurrent and retrospective review) and that payment for Facility services may be adjusted or denied for the inefficient delivery of services related to admissions, or length of stay.

Precertification and Referrals. Except when a Member requires emergency services, Facility agrees to comply with any applicable precertification and/or referral requirements under the Member's Plan prior to the provision of Facility services. Facility will utilize the electronic real time HIPAA compliant transactions, including but not limited to, eligibility, precertification and claim status inquiry transactions. Facility agrees to provide notice of all admissions of Members, and of all services for which Company requires notice, upon admission or prior to the provision of such services. For the purpose of pre-admission testing, Facility agrees to directly provide testing or accept test results and examinations performed outside Facility, provided such tests and examinations are: (a) performed by a state licensed laboratory for laboratory tests, and a licensed physician for such other tests and examinations; and (b) performed within a time reasonably proximate to the admission. For those Members who require services under a specialty program, Facility agrees to work with Company in transferring the Member's care to a specialty program Facility, as the case may be.

4. Provider Manual

These requirements are also referenced in Aetna's Provider Manual, applicable to its participating providers. Please see Appendix A for Provider Manual provisions applicable to retrospective review.

5. Policies and Procedures

The following internal policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address retrospective review:

- **NCS 100: Precertification P&P** – Aetna's policy defining precertification and providing the rules and processes for applying clinical criteria/guidelines to covered benefits for eligible members during the pre-service review process.
- **NCS 300: Retrospective Review P&P** – Aetna's policy outlining when retrospective review is conducted and the process that staff follow to conduct retrospective review.
- **Aetna Timely Notification of Hospital Admissions Payment Policy** – Aetna's payment policy, applicable to Aetna's participating providers, which specifies the timely notification requirements for inpatient admissions for acute medical-surgical hospitals.
- **NCS 527: Emergency Services and Call Handling Policy and Procedure –** Aetna policy providing for retrospective review of designated emergency services claims.
    - **National Clinical Services (NCS) 527 Emergency Services and Call Handling Policy and Procedure – Virginia**
        - This amendment will be used in conjunction with NCS 527 to comply with Virginia requirements.
- **NCS 503: Medical Review P&P** – Aetna policy that explains the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
    - **National Clinical Services (NCS) 503 Medical Review – Virginia**
        - This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
- **NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy** – Aetna's policy outlining the timeliness standards for notifying members and providers of coverage decisions.
    - **National Clinical Services (NCS) 504 Timeliness Standards for Coverage Decisions and Notification Policy - Virginia**
        - This amendment will be used in conjunction with NCS 504 to comply with Virginia requirements.
- **NCS 505: Denial of Coverage Policy and Notification** – Aetna policy defining and outlining the handling of denial of coverage determinations.
    - **National Clinical Services NCS 505: Denial of Coverage Policy and Notification – Virginia**

        - This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements.

- **NCS 506: Peer-to-Peer Review Policy** – Aetna policy that describes the process for treating practitioners/clinicians/physicians to discuss a clinical denial with a peer reviewer or behavioral health consultant/psychiatrist/psychologist.
    - **National Clinical Services NCS 506: Peer-to-Peer Review – Virginia**
        - This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.

- **NCS 510: Internal Quality Review Policy** – Aetna policy describing the internal quality review process to assess the compliance with policies and procedures of individuals who support the health plan's medical management programs.

Additionally, Aetna's **Clinical Claim Review Program Description** describes when retrospective review is conducted for emergency room services. More broadly, Aetna's Care Management Program Description ("**UM Program Description**"), which applies to M/S and MH/SUD benefits, encompasses Aetna's utilization management program. The UM Program Description defines the scope, goals and objectives, processes, and monitoring of retrospective review and other utilization management programs.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Overview

The group of services to which retrospective review applies, for inpatient and outpatient OON benefits and INN benefits, are services for which precertification was required, but was not obtained.

- For INN benefits, precertification applies to inpatient admissions and select ambulatory procedures and services. Precertification applies to 1) services on the Aetna Participating Provider Precertification List, 2) services on the Aetna Behavioral Health Precertification List, and 3) any other services that require precertification under the terms of the member's plan (typically applicable to self-insured plans). The Aetna Participating Provider Precertification List and Aetna Behavioral Health Precertification List are referred to collectively as the National Precertification List (NPL). The most current versions are publicly available online.[1] Please see Aetna's INN Precertification NQTL Comparative Analysis for further information, including the list of applicable services.

[1] www.aetna.com/health-care-professionals/precertification/precertification-lists.html

- For OON benefits, precertification applies to inpatient admissions and certain outpatient services and supplies. Precertification applies to the services listed in the member's certificate of coverage, referred to as the Member Precertification List (MPL). Please see Aetna's OON Precertification NQTL Comparative Analysis for further information including the listing of applicable services.

Retrospective review applies to the following M/S and MH/SUD services for which precertification was required but was not obtained: 1) all **out-of-network inpatient** services and all **out-of-network outpatient–all other** services; 2) **in-network inpatient** and **outpatient–all other** services when required conditions are met as discussed below. Retrospective review also applies to **emergency** services where the M/S and MH/SUD diagnosis codes submitted on an emergency claim signify a condition that potentially was not an emergency as defined pursuant to the federal "prudent layperson" standard, as listed in Aetna's Non-Emergent ER Diagnosis Codes List.

Benefits and Classification

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **INN OP AO** ✔ **OON IP** ✔ **OON OP AO** ✔ **Emergency**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
INN Inpatient All inpatient admissions, including hospital, skilled nursing facilities, and rehabilitation facilities for which precertification was required but was not obtained can be subject to retrospective review when the required conditions are met.	**INN Inpatient** All inpatient admissions, including residential treatment facilities for which precertification was required but was not obtained can be subject to retrospective review when the required conditions are met.
INN Outpatient – All Other All outpatient–all other services on the NPL that were not precertified can be subject to retrospective review when the required conditions are met. These services are too numerous to list; please see the NPL.	**INN Outpatient – All Other** All outpatient–all other services on the NPL that were not precertified can be subject to retrospective review when the required conditions are met. These services are: • Applied Behavioral Analysis (ABA) for autism spectrum disorder • Transcranial Magnetic Stimulation • Partial Hospitalization (PHP) • Gender Affirmation Surgery
OON Inpatient All inpatient admissions, including hospital, skilled nursing facilities, rehabilitation facilities and hospice facilities, for which precertification was required, but was not obtained.	**OON Inpatient** All inpatient admissions, including residential treatment facilities, for which precertification was required but was not obtained.
OON Outpatient-All Other All outpatient–all other services on the MPL that were not precertified. These services are: • Advanced reproductive technology (ART) services • Complex imaging • Cosmetic and reconstructive surgery	**OON Outpatient-All Other** All outpatient–all other services on the MPL that were not precertified. These services are: • Applied behavioral analysis (ABA) • Gender affirming treatment • Partial hospitalization program (PHP) • Transcranial magnetic stimulation (TMS)

• Gene-based, cellular and other innovative therapies (GCIT) • Home health care • Hospice care • Injectables (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications) • Kidney dialysis • Knee surgery • Limited infertility services • Non-emergency transportation by airplane • Obesity (bariatric) surgery • Outpatient back surgery not performed in a physician's office • Private duty nursing services • Sleep studies • Wrist surgery	
Emergency Services rendered in the Emergency Department where all M/S and MH/SUD diagnosis codes on the claim are on Aetna's Non-Emergent ER Diagnosis Code List.	**Emergency** Services rendered in the Emergency Department where all M/S and MH/SUD diagnosis codes on the claim are on Aetna's Non-Emergent ER Diagnosis Code List.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of retrospective review. Each subpart includes,* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to retrospective review, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL.

Factor	Applicable to M/S	Applicable to MH/SUD
Cost management	✓	✓
Clinically appropriate utilization	✓	✓

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

- **Clinically appropriate utilization** is a **factor** that seeks to ensure that M/S and MH/SUD treatments, procedures, or services are appropriate for the diagnosis, severity of illness, and overall health status of a patient, and that they are provided in accordance with evidence-based guidelines and practices that are relevant to the condition being treated and that avoids misuse of care.

In accordance with Aetna's standard certificate of coverage, for services to be medically necessary, they should be "clinically appropriate, in terms of type, frequency, extent, site, place of service, duration, and considered effective for your illness, injury, or disease." In general, the following **sources** contain the **evidentiary standards** (i.e., clinical treatment guidelines) that are used in the design of this NQTL to support the **factor** of clinically appropriate utilization. However, for insured plans, a state law may require Aetna to apply an alternative standard:

- MCG Health Care Guidelines
- National Comprehensive Cancer Network Treatment guidelines
- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS)
- Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII)
- Aetna's Applied Behavioral Analysis Medical Necessity Guide
- Aetna Clinical Policy Bulletins

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL when (a) determining services subject to retrospective review – INN; (b) determining services subject to retrospective review – OON; (c) determining services subject to retrospective review – emergency; and (d) the process of how retrospective review is performed.

(a) Factors for determining services subject to retrospective review – In-network benefits (inpatient and outpatient–all other)

Factor	Applicable to M/S	Applicable to MH/SUD
Services for which precertification is required, but was not obtained	✓	✓
Inpatient admission type	✓	✓
State and federal law	✓	✓
Participating provider contract terms	✓	✓
Valid administrative reason for failure to precertify or give timely notification	✓	✓

- **Services for which precertification is required, but was not obtained,** is a **factor** that defines the group of services to which retrospective review may apply if other conditions are met. The additional factors discussed below describe the limited circumstances representing *when* retrospective review is conducted for INN services for which precertification is required, but was not obtained. The **evidentiary standards and sources** upon which this factor is based are:
    - The INN M/S services and MH/SUD services to which precertification applies. For INN benefits, precertification applies to inpatient admissions and certain outpatient procedures and services listed on the NPL as above defined.
    - The factors, evidentiary standards, and sources for determining services for which precertification is required, as implemented through the Aetna policies, procedures and other materials discussed at length in Aetna's INN Precertification NQTL Comparative Analysis.

- **Inpatient admission type** is a **factor** used to evaluate whether inpatient services are subject to retrospective review. Inpatient admission type refers to whether the inpatient admission was elective or an emergency. Aetna conducts retrospective review of inpatient hospital admissions resulting from an emergency where the hospital complies with Aetna's notification requirements for such admissions. The **evidentiary standards and sources** upon which this factor is based are:
    - An elective inpatient admission refers to planned care in an inpatient setting. An emergency inpatient admission is one where the physician admits the person to the hospital or treatment facility right after the sudden and unexpected onset of a change in a person's physical or mental condition which requires confinement right away as a full-time inpatient.
    - Retrospective review is performed on claims submitted by INN hospitals that meet Aetna's notification requirements for emergency admissions, pursuant to Aetna's NCS 300: Retrospective Review Policy and Timely Notification of Hospital Admissions Payment Policy for participating providers.

The following **additional factors** also provide a basis for Aetna to conduct retrospective review for INN services (inpatient and outpatient–all other).

- **State and federal law** – Aetna monitors state and federal laws and disaster declarations, to determine when Aetna's standard obligation for providers to obtain precertification or provide timely notification for inpatient admissions and outpatient services on the NPL must be waived, and complies with all such requirements. When a provider renders a service for which Aetna requires precertification or timely notice, but the requirement must be waived pursuant to state or federal law and/or disaster declaration, Aetna will conduct a retrospective review of the service. The **evidentiary standards and sources** upon which this factor is based are:
    - State and federal laws and/or disaster declarations pertaining to waiver of INN provider precertification and/or timely notification requirements.

- **Participating provider contract terms –** Aetna monitors the terms of its contracts with participating providers for any deviations from Aetna's standard contractual terms which require participating providers to obtain precertification or provide timely notification for inpatient admissions and outpatient services listed on the NPL. The **evidentiary standards and sources** upon which this factor is based are:
    - The terms of the individual participating provider contracts that set forth the obligations of Aetna's participating providers with respect to precertification and timely notification, and by extension, retrospective review. Where contract terms require that the standard obligation for providers to obtain precertification and/or provide timely notification of a service must be waived, Aetna will conduct retrospective review of the service.

- **Valid administrative reason for failure to precertify or give timely notification –**refers to instances in which a provider has a valid reason for failure to precertify or give timely notification of a service. In such instances, where the provider has a valid reason for the failure to precertify or give timely notice, Aetna will conduct retrospective review of the service. The **evidentiary standards and sources** upon which this factor is based are:
    - Aetna considers the following to constitute a valid reason for failure to precertify or provide timely notification for an applicable service: 1) a patient is unable to provide insurance information due to their clinical condition or a language barrier; 2) an unattended minor requires immediate medical treatment; 3) a patient provides incorrect insurance information; 4) a self-funded plan requires enrollment of a newborn for continued coverage after a maternity stay; 5) a newborn is detained after the mother's discharge; 6) a mother requires more inpatient care than the standard maternity stay (3 days total for a vaginal birth or 5 days total for a cesarean birth).

(b) Factors for determining services subject to retrospective review – Out-of-network benefits (inpatient and outpatient–all other)

Factor	Applicable to M/S	Applicable to MH/SUD
Services for which precertification is required, but was not obtained	✓	✓

- **Services for which precertification is required, but was not obtained –** Aetna conducts retrospective review on all M/S and MH/SUD services for which precertification is required, but was not obtained. The **evidentiary standards and sources** upon which this factor is based are:
    - The M/S services and MH/SUD services listed in the MPL located in the member's certificate of coverage. Precertification applies to inpatient admissions and certain outpatient services and supplies, as listed in the MPL.

- The factors, evidentiary standards, and sources for determining services for which precertification is required, as implemented through the Aetna policies, procedures and other materials discussed at length in Aetna's OON Precertification NQTL Comparative Analysis.

(c) Factors for determining services subject to retrospective review – Emergency

Factor	Applicable to M/S	Applicable to MH/SUD
Federal law	✓	✓
Applicable state law	✓	✓

- **Federal law** consists of regulatory and legal requirements defining the "prudent layperson" standard for emergency services. The **evidentiary standards and sources** upon which this factor is based are:
  - Applicable federal laws and regulations, specifically, The Balanced Budget Act of 1997, and the definition of the "prudent layperson" policy and standard with respect to emergency services, as implemented through Aetna Policy NCS 527: Emergency Services Policy and Procedure.

- **Applicable state law** refers to applicable regulatory and legal requirements concerning retrospective review of emergency services. The **evidentiary standards and sources** upon which this factor is based are:
  - Applicable state law requirements concerning retrospective review of emergency services, as acknowledged pursuant to Aetna Policy NCS 527: Emergency Services Policy and Procedure, and Controlling State Guidelines.

(d) Factors for the process of performing retrospective review

Factor	Applicable to M/S	Applicable to MH/SUD
NCQA Guidelines and Standards	✓	✓
Generally accepted standards of medical practice and clinical appropriateness	✓	✓
Applicable state and federal law	✓	✓

- **National Committee for Quality Assurance (NCQA) Accreditation Standards –** NCQA sets utilization management standards for Health Plan accreditation and Managed

Behavioral Health Organization accreditation. The **evidentiary standards and sources** upon which this factor is based are:

- Timeliness and clinical review standards that Aetna sets to meet NCQA Guidelines and Standards, as implemented through Aetna Policies NCS 503: Medical Review P&P and NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P and the applicable Virgina state amendments.
- NCQA Health Plan Accreditation and MBHO Utilization Management Standards and Guidelines, Clinical Criteria for UM Decisions, Appropriate Professionals, Timeliness of UM Decisions, and Clinical Information.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in our clinical policies and applying clinical judgment. In general, the following **sources** contain the **evidentiary standards** (i.e., clinical treatment guidelines) utilized by Aetna's clinicians during the retrospective review determination process:
  - Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
  - MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
  - National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
  - American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
  - Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
  - Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
  - Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
  - "Prudent layperson" standard and applicable state law standards to define emergency care

- **Applicable state and federal law** are regulatory and legal requirements concerning the retrospective review process. The **evidentiary standards and sources** upon which this factor is based are:
    - Time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations, as implemented through Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification P&P.
    - Timeframes set forth in applicable state law that require certain turnaround times for retrospective review decisions in some states. State law or regulation that mandates a more stringent response time supersedes Aetna's national standard, as implemented through NCS 504: Timeliness Standards for Coverage Decisions and Notifications P&P, and are acknowledged in state amendments to the corresponding NCS P&Ps.
    - Specific medical necessity guidelines set forth in applicable law. Insured plans in a state that requires use of specific medical necessity guidelines are administered in accordance with the state's requirements, and are acknowledged in state amendments to the corresponding NCS P&Ps.
    - Other state law requirements applicable to retrospective review.

Step 3: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Cost management** is a factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management applies equally to all M/S and MH/SUD benefits. Cost management generally underlies Aetna's determination that M/S and MH/SUD inpatient services and selected outpatient services require precertification, and by extension, may be subject to retrospective review.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: With respect to cost management, the evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. Since Aetna's entrance into the insurance and health plan administration business, cost management has been and continues to be a significant operating consideration. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (*see, e.g.,* Form 10-K at page 34 "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of retrospective review, cost management does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

- **Clinically appropriate utilization** is a factor and strategy underlying the design of retrospective review, seeking to ensure the plan covers medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In accordance with Aetna's standard certificate of coverage, medically necessary health care services are those that are clinically appropriate in terms of type, frequency, extent, site, place of service, duration, and considered effective for the member's illness, injury, or disease.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of clinically appropriate utilization applies equally to all M/S and MH/SUD benefits. This design factor aligns to the use of uniform evidentiary standards to assess the clinical appropriateness of a particular service, discussed in more detail below.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL****:* The evidentiary standards considered and relied upon when designing this NQTL are those generally accepted standards of care identified above in Step 2, Part 1 (e.g., MCG, LOCUS, CALOCUS). For M/S benefits, the assessment of

whether care is clinically appropriate in the context of retrospective review relies on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. For MH/SUD benefits, clinically appropriate utilization is based on the American Society of Addiction Medicine (ASAM) Criteria: *Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilizations System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), Aetna's Applied Behavioral Analysis Medical Necessity Guide, and the appropriate Aetna MH/SUD Clinical Policy Bulletins. Please see Aetna's Medical Necessity NQTL Comparative Analysis for a detailed analysis of the factors, evidentiary standards and sources relied upon to adopt Aetna's medical necessity criteria. For emergency services, applicable to both M/S and MH/SUD diagnoses, the assessment relies on the "prudent layperson" standard and applicable state law standards to define emergency care.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of retrospective review, clinically appropriate utilization does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of clinically appropriate utilization, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of cost management and clinically appropriate utilization apply equally and agnostically to both M/S and MH/SUD benefits in the general design of retrospective review. They are interrelated because they collectively seek to ensure that the plan covers only medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective retrospective review process. Similarly, no one factor is weighted more than another in the design of retrospective review.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137 (c)(3)]

The following describes how factors are used in the application of retrospective review for: (a) determining services subject to retrospective review – INN; (b) determining services subject to retrospective review – OON; (c) determining services subject to retrospective review – emergency; and (d) the process of how retrospective review is performed.

(a) Factors for determining services subject to retrospective review – In-network benefits (inpatient and outpatient–all other)

- **Services for which precertification is required, but was not obtained** defines the group of services to which retrospective review may apply if other conditions are met.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. This factor defines the group of services to which retrospective review may apply if other conditions are met. The additional factors listed below describe the limited circumstances representing *when* retrospective review is conducted for INN services for which precertification is required, but was not obtained.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL****:* For INN benefits, precertification is required for inpatient admissions and certain outpatient services as listed on Aetna's NPL. The factors, evidentiary standards, and sources for determining services for which precertification is required, as implemented through Aetna policies, procedures, and other materials, are discussed in detail in Aetna's INN Precertification NQTL Comparative Analysis.
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits. If an INN service requires precertification, but precertification was not obtained, the service is subject to retrospective review under the circumstances addressed through the remaining factors.
    (d) ***Deviations or variations from a factor:*** There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **Inpatient admission type** refers to whether the inpatient admission was elective or an emergency.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor is used in determining the inpatient services that are subject to retrospective review as explained below. Inpatient admission type refers to whether an inpatient admission was elective or an emergency. Aetna conducts retrospective review of inpatient hospital admissions resulting from an emergency where the hospital complies with Aetna's notification requirements for such admissions.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL:*** An elective inpatient admission refers to planned care in an inpatient setting. An emergency inpatient admission is one where the physician admits the person to the hospital or treatment facility right after the sudden and unexpected onset of a change in a person's physical or mental condition which requires confinement right away as a full-time inpatient. Precertification is required for all non-emergency, or elective, admissions. In addition, when a member requires an emergency hospital admission, INN providers are required to notify Aetna of the admission pursuant to Aetna's timely notification requirements set forth in Aetna's Timely Notification of

Hospital Admissions Payment Policy. The Timely Notification Policy applies to acute medical-surgical hospitals and requires that acute medical-surgical hospitals notify Aetna within two business days of an inpatient admission. The Timely Notification Policy applies equally to M/S and MH/SUD services provided at acute medical-surgical hospitals. Aetna conducts retrospective review of inpatient hospital admissions resulting from an emergency where the hospital complies with Aetna's notification requirements for such admissions.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: The Timely Notification Policy applies equally to M/S and MH/SUD services provided at acute medical-surgical hospitals. However, as a variation on this factor, Aetna does not require timely notification of an inpatient admission to a standalone acute psychiatric hospital. This means that instead of denying a claim or applying a late notification penalty for inpatient admissions to a standalone acute psychiatric hospital for which Aetna was not given notice, Aetna will conduct a retrospective review of the claim and pay the claim if the requirements for coverage are otherwise met.

The following **additional factors** also provide a basis for Aetna to conduct retrospective review for INN services (inpatient and outpatient–all other).

- **State and federal law** consists of regulatory and legal requirements pertaining to precertification and/or notification requirements.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna monitors state and federal laws and disaster declarations to determine when Aetna's standard obligation for a participating provider to obtain precertification or provide timely notification must be waived.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that is relied upon when applying this factor are state and federal regulations and/or the terms and requirements of disaster declarations pertaining to waiver of provider precertification and timely notification requirements. Aetna follows applicable state laws in the administration of precertification and retrospective review. More stringent state law requirements supersede Aetna's standard processes. Additionally, at times, a governmental body or official, including State Governors and Insurance Departments, may declare a State of Emergency or issue a Declaration or Proclamation requesting that insurance carriers relax certain policies so that citizens are not penalized for not being able to follow insurance procedures due to an emergency. Aetna complies with the required terms of such disaster declarations, whether the requirements are related to M/S or

MH/SUD services. When the obligation for a participating provider to obtain precertification or provide timely notification is waived, Aetna will perform retrospective review.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of state and federal law and/or disaster declarations pertaining to waiver of INN provider precertification and timely notification requirements and by extension performance of retrospective review, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Participating provider contract terms** refers to Aetna contracts with participating providers.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna monitors the terms of its contracts with participating providers for any deviations from Aetna's standard contractual terms which require participating providers to obtain precertification for inpatient admissions and outpatient services listed on the NPL and provide timely notice of relevant hospital admissions.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that is relied upon when applying this factor is the terms of the individual participating provider contracts that set forth the obligations of Aetna's participating providers with respect to precertification and timely notification, and by extension, retrospective review. Where contract terms require that the standard obligation for providers to obtain precertification or provide timely notification of a service must be waived, Aetna will conduct retrospective review of the service.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of participating provider contract terms pertaining to waiver of INN provider precertification and timely notification requirements and by extension performance of retrospective review, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Valid administrative reasons for failure to obtain precertification or give timely notification** refers to instances in which a provider has a valid reason for failure to precertify or give timely notification of a service.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: In instances where the participating provider has a valid reason for the failure to precertify or give timely notification, Aetna will conduct retrospective review of the service instead of denying the claim or imposing a payment penalty on the participating provider. This factor applies equally to M/S and MH/SUD services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Aetna specifies the scenarios which constitute a valid reason for failure to obtain precertification or provide timely notification which are:

- A patient is unable to provide insurance information due to their clinical condition or a language barrier;
- An unattended minor requires immediate medical treatment;
- A patient provides incorrect insurance information;
- A self-funded plan requires enrollment of a newborn for continued coverage after a maternity stay;
- A newborn is detained after the mother's discharge;
- A mother requires more inpatient care than the standard maternity stay (3 days total for a vaginal birth or 5 days total for a cesarean birth).

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: As set forth above, for INN services, because in-network providers are expected to comply with applicable precertification and timely notification requirements, Aetna performs retrospective review for INN services for which precertification was required, but was not obtained, in limited circumstances. The factor of "services for which precertification is required, but was not obtained" defines the group of services to which retrospective review may apply, if one of the other factors of 1) state and federal law pertaining to waiver of precertification and timely notification requirements; 2) participating provider contract terms; or 3) valid administrative reason for failure to precertify or give timely notification, is present and triggers retrospective review. Therefore, the factor of "services for which precertification was required was not obtained" is weighted more heavily and applies first, because it constitutes the category of services to which retrospective review may apply. Among the three additional factors, no factor is weighted more than the other as each would serve as an independent basis to conduct retrospective review. The factors set forth herein apply equally to M/S and MH/SUD services. Additionally, the factor of inpatient admission type operates as an independent basis on which retrospective review is predicated for inpatient hospital admissions.

(b) Factors for determining services subject to retrospective review – Out-of-network benefits (inpatient and outpatient–all other)

- **Services for which precertification is required, but was not obtained** refers to the group of services to which retrospective review applies.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna conducts retrospective review on all M/S and MH/SUD OON inpatient and outpatient–all other services for which precertification is required under the terms of the member's certificate of coverage, but was not obtained.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL:*** For OON benefits, precertification is required for the M/S services and MH/SUD services listed in the MPL located in the member's certificate of coverage. Precertification applies to inpatient admissions and certain outpatient services and supplies, as listed in the MPL. The factors, evidentiary standards, and sources for determining services for which precertification is required, as implemented through the Aetna policies, procedures, and other materials, are discussed in detail in Aetna's OON Precertification NQTL Comparative Analysis.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits. If an OON service requires precertification, but precertification was not obtained, Aetna will conduct a retrospective review.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

(c) Factors for determining services subject to retrospective review – Emergency

- **Federal law** consists of regulatory and legal requirements defining the "prudent layperson" standard for emergency services.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. This factor is used to determine emergency services subject to retrospective review. Aetna's Payment Policy and Coding Committee ("PPCC") evaluates this factor to develop Aetna's Non-Emergent ER Diagnosis Codes List, which consists of a list of M/S and MH/SUD ICD-10 (International Classification of Diseases, Tenth Revision) diagnosis codes that would not standardly be appropriate for an emergency room setting and signify that a condition may not have been an emergency under the "prudent layperson" standard. If all diagnosis codes on a claim submitted by a provider are on the Non-Emergent

ER Diagnosis Codes List, Aetna will conduct retrospective review to evaluate the claim and make a coverage determination regarding emergency room services.

The PPCC is responsible for the development of the Non-Emergent ER Diagnosis Codes list. ICD-10 codes are alphanumeric codes used to classify M/S and MH/SUD diagnoses and other health-related problems for billing and statistical purposes. The Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) maintain the ICD-10 classification system. The members of the PPCC apply their experience, clinical training, and professional judgment to identify the ICD-10 codes which, in the professional judgment of the PPCC, would not standardly be appropriate for an emergency room setting and signify that a condition may not have been an emergency under the "prudent layperson" standard. The PPCC conducts an annual review to determine if there are any new ICD-10 codes that should be added to the Non-Emergent ER Diagnosis Codes List. The PPCC is comprised of M/S and MH/SUD clinicians and other subject matter experts who represent a broad range of Aetna programs, and includes voting members from National Medical Policy & Operations Medical Directors, Commercial Clinical Specialty Operations Medical Directors, Local Market Medical Directors for all lines of business, Office of the Chief Medical Officer, Behavioral Health Medical Directors, National Medical Excellence, and Medicare Operations.

In addition, the PPCC includes optional non-voting members from various areas of the company, in order to gain diverse perspectives from across the organization as needed. Decisions are made by the PPCC by consensus when possible. If a consensus cannot be reached, the committee makes a decision by majority vote. The PPCC composition is included in Appendix F.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Applicable federal law, The Balanced Budget Act of 1997, defines an emergency medical condition as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

- Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman and her unborn child) in serious jeopardy; or,
- Serious impairment to bodily functions; or,
- Serious dysfunction of any bodily organ or part."

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There is no deviation or variation from the factor of federal law defining the "prudent layperson" standard for emergency

services, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **Applicable state law** refers to applicable regulatory and legal requirements concerning retrospective review of emergency services.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna follows applicable state law in the administration of retrospective review of emergency services. More stringent state law requirements supersede Aetna's standard processes. If a state law or regulation restricts Aetna from retrospectively reviewing emergency claims for that jurisdiction, Aetna does not retrospectively review those claims.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are the applicable state laws and regulations.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of applicable state law, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: As stated above, upon receipt of an emergency department claim, if all diagnosis codes on the claim are listed on Aetna's Non-Emergent ER Diagnosis Codes List, Aetna conducts retrospective review based on the medical records to determine whether the treatment was in fact for an emergency condition. In determining the emergency services that are subject to retrospective review, the factor of state law is weighted more heavily than the factor of federal law defining the prudent layperson standard, because if state law is more stringent than Aetna's procedures, and imposes a restriction on performing restrospective review on emergency services, Aetna complies with the state law and does not conduct retrospective review of claims for the applicable jurisdiction. These factors apply equally and agnostically to M/S and MH/SUD services.

(d) Factors for the process of performing retrospective review

The discussion below addresses the factors used in the process of performing retrospective review for M/S and MH/SUD services identified above as being subject to retrospective review.

- **National Committee for Quality Assurance (NCQA) Accreditation Standards -** NCQA sets utilization management standards for Health Plan accreditation and Managed Behavioral Health Organization accreditation.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna uses NCQA Health Plan and Managed Behavioral Health Organization Utilization Management Standards and Guidelines to adopt policies and procedures for the process of performing retrospective review for M/S and MH/SUD services. These policies are outlined in Step 4, Part 2.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: NCQA Standards and Guidelines require timeliness standards for performing retrospective review. Aetna's policy NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy & Procedure establishes the timeliness standards for issuing decisions, and these standards apply equally to M/S and MH/SUD services subject to retrospective review. These standards are outlined in Step 4, Part 2, and are contained in Attachment A of NCS 504. These standards are compliant with NCQA accreditation requirements for precertification, concurrent review and retrospective review. Additionally, the NCQA Standards and Guidelines include requirements pertaining to the clinical criteria used in decision making, the review of relevant medical records, and the involvement of appropriate personnel in decision making. These requirements are implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure and are discussed in detail in Aetna's Medical Necessity Nonquantitative Treatment Limitation Comparative Analysis.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Generally accepted standards of medical practice and clinical appropriateness** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and the standards set forth in our clinical policies.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to determine whether to approve coverage for M/S and MH/SUD retrospective review requests.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon are the following criteria/guidelines utilized by Aetna's clinical staff during the retrospective review determination process:

- Aetna Clinical Policy Bulletins (www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)
- MCG Health Care Guidelines (www.mcg.com/care-guidelines/care-guidelines/)
- National Comprehensive Cancer Network treatment guidelines (www.nccn.org/guidelines/category_1)
- American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition* (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Aetna's Applied Behavioral Analysis (ABA) Medical Necessity Guide (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services/ Child and Adolescent Service Intensity Instrument (CALOCUS-CASII) (www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html)
- "Prudent layperson" standard and applicable state law standards to define emergency care

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to determine whether to authorize coverage for M/S and MH/SUD retrospective review requests. This necessarily involves individualized evaluations and determinations for each patient and request for coverage. Please see Aetna's Medical Necessity NQTL Comparative Analysis for additional detail. Additionally, further information regarding the nature and timing of the determinations, as well as the designations and qualifications of the clinical staff is included herein in Step 4, Part 2. When making retrospective review decisions for M/S services, Aetna's clinical staff rely on MCG Health Care Guidelines, National Comprehensive Cancer Network Treatment guidelines, and applicable Aetna M/S Clinical Policy Bulletins. When making retrospective review decisions for MH/SUD services, Aetna's clinical staff rely on American Society of Addiction Medicine (ASAM) Criteria: *Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, 3rd Edition*, Aetna's Applied Behavioral Analysis Medical Necessity Guide, Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS), Child Adolescent Level of Care Utilization System for Psychiatric and Addictive Services / Child and Adolescent Service Intensity Instrument (CALOCUS-CASII), and the appropriate Aetna MH/SUD Clinical Policy

Bulletins. For emergency services, applicable to both M/S and MH/SUD conditions, the assessment relies on the "prudent layperson" policy and applicable state law standards to define emergency care. Additionally, Aetna considers the claim an emergency medical condition and pays it as such if the claim includes evidence of a referral from a physician, or evidence that an Aetna representative directed the member to an emergency room. Staff are required to document the specific clinical guidelines relied upon when making benefit determinations within their documentation notes.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of generally accepted standards of medical practice and clinical appropriateness, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Applicable state and federal law** are regulatory requirements related to the timeframes, use of specific medical necessity criteria, and other requirements applicable to retrospective review.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD services. Aetna complies with applicable state and federal required timeframes for performing retrospective review. Aetna's NCS 504 Policy establishes national standard timeframes which comply with time limits set by the Department of Labor (DOL)/Employee Retirement Income Security Act (ERISA) claims regulations. Aetna's NCS 503 Policy sets forth the medical necessity criteria used in reviewing retrospective review requests. State law or regulation that mandates a more stringent response time, use of specific medical necessity criteria, or other requirements applicable to retrospective review, supersedes Aetna's national standards**.**

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon are timeframes and specific medical necessity criteria that comply with applicable federal state and federal requirements for retrospective review requests. These standards are reflected in NCS 504 and NCS 503, and the state specific amendments to NCS 504 and NCS 503.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of applicable state and federal law, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Relationship, ordering and weighting of multiple factors: The factors listed above apply to distinct aspects of the process of performing retrospective review, including decision-making and the timeliness and medical necessity standards applicable thereto. The factors are interrelated, all

operate together to ensure that Aetna employs an appropriate and effective retrospective review process, and apply equally and agnostically to M/S and MH/SUD services. Aetna's national standards discussed above and set forth in NCS policies and procedures are based upon NCQA accreditation requirements and generally accepted standards of medical practice and clinical appropriateness. However, applicable law is weighted more heavily, as applicable law or regulation that mandates a more stringent response time, use of specific medical necessity criteria, or other requirements applicable to retrospective review, supersedes Aetna's national standards for applicable plans.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2, that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, Aetna conducts retrospective review of M/S and MH/SUD services for which precertification was required but was not obtained, for all OON inpatient and outpatient claims and for a limited set of INN inpatient and outpatient claims. Additionally, Aetna conducts retrospective review of emergency claims for which the submitted MH/SUD and M/S diagnosis codes signify a condition that potentially was not an emergency as defined pursuant to the federal "prudent layperson" standard. Accordingly, retrospective review applies to the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient–all other; 3) out-of-network inpatient; 4) out-of-network outpatient–all other; and 5) emergency. As noted in

Step 2, Part 1, two factors were used in the context of designing retrospective review: 1) cost management and 2) clinically appropriate utilization, both of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services in all applicable benefit classifications. Promotion of cost management and clinically appropriate utilization are general design concepts and are a basis and rationale underlying Aetna's policies related to retrospective review for M/S and MH/SUD services. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, both factors apply equally to both benefit types.

These general design factors are evidenced through general acknowledgement of cost management as a factor in CVS Health public filings noted in Step 3, Part 1, and the specific clinical guidelines identified in Step 2, Part 1, that reflect the clinically appropriate guidelines for both M/S and MH/SUD services. Additionally, Aetna's **UM Program Description** provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." While these materials refer to the general design factors of promotion of cost management and clinically appropriate utilization, there is no written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of retrospective review with respect to M/S and MH/SUD benefits.

These factors apply equally to both benefit types and are not applied incomparably, or more stringently, to MH/SUD benefits in the applicable benefit classifications. Similarly, there are no deviations or variations from these two factors, as they apply to the design of retrospective review. Aetna's analysis shows that as written, the processes, strategies, evidentiary standards or other factors used in designing retrospective review with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing retrospective review with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 2, Part 2, different factors are applied in the context of retrospective review for: (a) determining services subject to retrospective review – INN; (b) determining services subject to retrospective review – OON; (c) determining services subject to retrospective review – emergency; and (d) the process of how retrospective review is performed. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying retrospective review to MH/SUD benefits are comparable to, and are applied no more

stringently than, the processes, strategies, evidentiary standards and other factors used in applying retrospective review with respect to M/S benefits.

(a) Determining services subject to retrospective review – In-network benefits (inpatient and outpatient–all other)

As set forth in Step 2, Part 2, the factors used in the application of retrospective review, to determine in-network benefits subject to retrospective review are: 1) services for which precertification is required, but was not obtained; 2) inpatient admission type; 3) state and federal law pertaining to waiver of precertification and/or timely notification requirements; 4) participating provider contract terms; and 5) valid administrative reason for failure to precertify or provide timely notification. As set forth in Step 3, Part 2, Aetna's participating providers are contractually required and expected to comply with applicable precertification and timely notification requirements. If precertification requirements and/or notification requirements are not followed, the claim is generally denied for lack of precertification or notification, unless subject to retrospective review as set forth herein. As written in Aetna's provider and facility contracts, and included in Step 1, Part 1, no in-network provider is permitted to bill the member if precertification or timely notification obligations are not met. Aetna conducts retrospective review of INN M/S and MH/SUD benefits in limited circumstances as detailed herein based upon the above-referenced factors, including the application of the same through Aetna's written materials. Aetna's analysis of applicable written materials demonstrates that the processes, strategies, evidentiary standards or other factors used to apply retrospective review to MH/SUD benefits are comparable to, and no more stringently applied than, those used to apply retrospective review to M/S benefits.

Aetna policy **NCS 300: Retrospective Review Policy and Procedure** outlines when retrospective review is conducted and the process that staff follow to conduct retrospective review. As noted in the scope of the policy, it applies to M/S and MH/SUD (called behavioral health) services. Pursuant to NCS 300, for both M/S and MH/SUD services, Aetna performs retrospective review for inpatient and outpatient benefits when Aetna receives a claim for a procedure or service requiring precertification, for which precertification is not found, and the claim is eligible for review after the date of service. Pursuant to NCS 300, the group of M/S and MH/SUD services eligible for retrospective review are claims for which precertification is required but was not obtained prior to the service. Additionally, NCS 300 distinguishes between elective and emergency inpatient services, and refers to the requirement that elective inpatient services must be pre-certified, and emergency inpatient services must meet Aetna's timely notification requirements.

Relating to inpatient admissions, Aetna's timely notification requirements are set forth in its **Timely Notification of Hospital Admissions** Payment Policy. The Timely Notification Policy applies to acute medical-surgical hospitals and requires that acute medical-surgical hospitals notify Aetna of an inpatient admission within two business days. If the in-network provider notifies Aetna

late, a late notification payment penalty applies. If the in-network provider does not notify Aetna at all, Aetna may deny the claim for lack of notification. The Timely Notification Policy applies equally to M/S and MH/SUD services provided at acute medical-surgical hospitals, for example, a general hospital with a psychiatric unit. Pursuant to NCS 300, Aetna conducts retrospective review of inpatient hospital admissions for M/S or MH/SUD services resulting from an emergency where the hospital complies with Aetna's notification requirements for such admissions. However, as a variation on this factor, the Timely Notification of Hospital Admissions Policy does not apply to, and Aetna does not require timely notification of, an inpatient admission to a standalone acute psychiatric hospital. This means that instead of denying a claim for inpatient admissions to a standalone acute psychiatric hospital for which Aetna was not given notice, Aetna will conduct a retrospective review of the claim and pay the claim if the requirements for coverage are otherwise met. Because conducting a retrospective review is a less stringent alternative to denying a claim for failure to comply with precertification or timely notification requirements, this variation represents a less, not more, stringent application of a treatment limitation with respect to MH/SUD inpatient benefits than M/S benefits.

Additionally, where an in-network provider fails to comply with precertification or notification requirements, for all M/S and MH/SUD inpatient and outpatient–all other services, Aetna conducts retrospective review where specified additional circumstances are present that either waive, or excuse failure to comply, with the requirements. NCS 300 refers to circumstances under which claims are to be retrospectively reviewed as opposed to administratively denied for failure to meet notification requirements. These bases for retrospective review correspond to the factors of: a) state and federal law pertaining to waiver of precertification and/or timely notification requirements; b) participating provider contract terms, and c) valid administrative reason for failure to precertify or provide timely notification. These bases for retrospective review and factors apply equally to M/S and MH/SUD services.

Aetna follows applicable state laws in the administration of precertification and retrospective review. More stringent state law requirements supersede Aetna's standard retrospective review processes, as documented pursuant to NCS 300 and Aetna's Controlling State guidelines. Aetna follows such applicable state laws with regard to any application to M/S or MH/SUD benefits. Additionally, when a governmental body or official, including a State Governor or Insurance Department, declares a State of Emergency or issues a Declaration or Proclamation requesting that insurance carriers relax certain policies so that citizens are not penalized for not being able to follow insurance procedures due to an emergency, Aetna maintains processes to track and document such requirements. Aetna complies with the required terms of such disaster declarations, for all impacted benefits. When the obligation for a participating provider to obtain precertification or provide timely notification is waived, Aetna will perform retrospective review. With regard to participating provider contract terms, Aetna monitors the terms of its contracts with participating providers for any deviations from Aetna's standard contractual terms which require participating providers to obtain precertification for M/S and MH/SUD inpatient admissions and

outpatient services listed on the NPL and provide timely notice of relevant M/S and MH/SUD hospital admissions. When the obligation to obtain precertification or provide timely notification is waived, Aetna will perform retrospective review of the service.

Finally, Aetna recognizes instances in which a participating provider has a valid reason for failure to precertify or give timely notification of a relevant M/S or MH/SUD service. In such instances, Aetna will conduct retrospective review of the service instead of denying the claim. The circumstances recognized by Aetna to consist of a valid reason are: 1) a patient is unable to provide insurance information due to their clinical condition or a language barrier; 2) an unattended minor requires immediate medical treatment; 3) a patient provides incorrect insurance information; 4) a self-funded plan requires enrollment of a newborn for continued coverage after a maternity stay; 5) a newborn is detained after the mother's discharge; and 6) a mother requires more inpatient care than the standard maternity stay (3 days total for a vaginal birth or 5 days total for a cesarean birth). As required by NCS 300, participating providers are directed to send an explanation to Aetna with the request for payment as to why the precertification requirement was not met. Although reasons 4-6 relate to newborn/maternity care and therefore would not likely be applicable to MH/SUD services, the remaining reasons are equally applicable to MH/SUD and M/S services.

The factors of 1) services for which precertification is required, but was not obtained; 2) inpatient admission type; 3) state and federal law pertaining to waiver of precertification and/or timely notification requirements; 4) participating provider contract terms; and 5) valid administrative reason for failure to precertify or provide timely notification, are applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Accordingly, Aetna's analysis of the "as written" material used to apply retrospective review and determine which INN benefits are subject to retrospective review, shows that the factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(b) Determining services subject to retrospective review – Out-of-network benefits (inpatient and outpatient–all other)

As set forth in Step 2, Part 2, the factors used in the application of retrospective review, to determine OON benefits subject to retrospective review are: 1) services for which precertification is required, but was not obtained. As set forth above, Aetna conducts retrospective review on all OON inpatient and outpatient–all other services for which precertification is required, but was not obtained. Aetna's analysis of applicable written materials demonstrates that the processes, strategies, evidentiary standards or other factors used to apply retrospective review to MH/SUD benefits are comparable to, and no more stringently applied, than those used to apply retrospective review to M/S benefits.

Aetna Policy **NCS 300: Retrospective Review Policy and Procedure** outlines when retrospective review is conducted and the process that staff follow to conduct retrospective review. As noted in the scope of the policy, it applies to M/S and MH/SUD (called behavioral health) services. Pursuant to NCS 300, for both M/S and MH/SUD services, Aetna performs retrospective review when Aetna receives a claim for a procedure or service requiring precertification, for which precertification is not found, and the claim is eligible for review after the date of service. Retrospective review applies to all M/S and MH/SUD services and procedures that require precertification under the terms of a member's plan, or the MPL as defined above, for which precertification was not obtained. These services include inpatient admissions and certain outpatient services and supplies, as listed in the MPL. NCS 300 applies equally to M/S and MH/SUD benefits, as it relates to OON services for which retrospective review is conducted. Accordingly, Aetna's analysis of the "as written" material used to apply retrospective review and determine which OON benefits are subject to retrospective review, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(c) Determining services subject to retrospective review – Emergency

As set forth in Step 2, Part 2, the factors used in the application of retrospective review to determine emergency services subject to retrospective review are: 1) federal law defining the "prudent layperson" standard for emergency services and 2) applicable state law. As set forth above, Aetna conducts review of emergency services based upon the above-referenced factors and the application of the same through Aetna's written materials. Specifically, Aetna conducts retrospective review of services rendered in the emergency department where all M/S and MH/SUD diagnosis codes on the claim are on Aetna's Non-Emergent ER Diagnosis Code List. Aetna's analysis of applicable written materials demonstrates that the processes, strategies, evidentiary standards or other factors used to apply retrospective review to emergency services are comparable with respect to M/S and MH/SUD conditions.

Aetna Policy **NCS 527: Emergency Services and Call Handling Policy and Procedure and the VA amendment** provide for retrospective review of designated emergency services claims. As noted in the scope of the policy, it applies to M/S and MH/SUD (called behavioral health). Pursuant to NCS 527, Aetna retrospectively reviews designated claims for emergency services prior to claim adjudication, the review of which may include documentation of the member's presenting symptoms and discharge diagnoses. Similarly, **Aetna's Provider Manual** notes that "[c]laims submitted to us by the provider that supplied care must appear to meet the standards for emergency or urgent care. Otherwise, we may need to review the records from the emergency visit. In this situation we will send a request to the treating facility for the records of the visit and notify the member of the request. If the member wishes, they may provide us with additional information regarding the circumstances of the visit." Both NCS 527 and the Provider

Manual indicate that Aetna provides coverage for emergency services following the "prudent layperson" emergency policy set forth in the Balanced Budget Act of 1997 and any applicable state law standards. As set forth above, the federal law defines an emergency medical condition as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: 1) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman and her unborn child) in serious jeopardy; or, 2) serious impairment to bodily functions; or, 3) serious dysfunction of any bodily organ or part.

Aetna's **Clinical Claim Review Program documentation** further acknowledges the applicability of the "prudent layperson" standard, and notes that state-specific variations may apply. Further, this documentation specifies that on initial claim submission, Aetna conducts retrospective review if all diagnosis codes on the claim are on the Non-Emergent ER Diagnosis Codes List, and the provider submits documentation for review (ER record and/or patient statement). Aetna's PPCC, which includes both M/S and MH/SUD clinical representation, evaluates the "prudent layperson" standard and ICD-10 diagnosis codes. PPCC members apply their experience, clinical training, and professional judgment to identify M/S and MH/SUD codes which in the professional judgment of the PPCC, would not standardly be appropriate for an emergency room setting and signify that a condition may not have been an emergency under the "prudent layperson" standard, and identify the same pursuant to Aetna's Non-Emergent ER Diagnosis Codes List. Importantly, for 2025, of the 1,808 diagnosis codes that trigger retrospective review, only 106 (5.9%) are for MH/SUD conditions. Therefore, over 94% of the total codes that trigger retrospective review of emergency services pertain to M/S conditions as opposed to MH/SUD conditions.

The written materials discussed herein apply equally to M/S and MH/SUD conditions. Aetna's analysis of the "as written" material used to apply retrospective review and determine which emergency benefits are subject to retrospective review, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD conditions and not more stringently applied to MH/SUD conditions.

(d) The process of performing retrospective review

As set forth above in Step 2, Part 2, the factors used in application, for the process of performing retrospective review are: 1) NCQA accreditation standards; 2) applicable state and federal law; and 3) generally accepted standards of medical practice and clinical appropriateness. Aetna conducts retrospective review based upon the above-referenced factors and the application of the same through Aetna's written materials. These processes are described in detail in the Aetna Utilization Management policies and procedures pertaining to retrospective review. Aetna maintains one set of written UM policies that are equally applicable to M/S and MH/SUD and

represent the strategies and processes that Aetna employs to perform retrospective review for M/S and MH/SUD services:

- NCS 300: Retrospective Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure – VA amendment
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy
- NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy – VA amendment
- NCS 505: Denial of Coverage Policy and Notification
- NCS 505 Denial of Coverage Policy and Notification – VA amendment
- NCS 506: Peer-to-Peer Review Policy
- NCS 506: Peer-to-Peer Review Policy – VA amendment
- NCS 510: Internal Quality Review Policy
- NCS 527: Emergency Services and Call Handling Policy & Procedure
- NCS 527: Emergency Services and Call Handling Policy & Procedure – VA amendment

Each of these policies is discussed in turn below, demonstrating that they are comparably applied, as written, to MH/SUD and M/S services.

NCS 300 applies to M/S and MH/SUD services, and outlines when retrospective review is conducted and the process that staff follow to conduct retrospective review. Aetna performs retrospective reviews after confirming member eligibility and the availability of benefits on the date(s) of service. With respect to how retrospective review requests are administered, staff use criteria/guidelines to make retrospective coverage determinations following NCS 503 within the retrospective timeframes in NCS 504, both discussed below. While NCS 300 refers to separate UM units that handle M/S and MH/SUD requests, the processes followed by those units are comparable and no more stringently applied to MH/SUD.

NCS 503 establishes the process of medical review and establish the written clinical criteria/guidelines used by Aetna's clinicians in making medical necessity determinations. This policy applies equally to M/S and MH/SUD services. For both M/S and MH/SUD services, the guiding strategy behind retrospective review relies upon the clinical reviewers' exercise of their clinical judgment, guided by clinical criteria, to determine whether to authorize coverage for requests. While NCS 503 sets forth separate written guidelines that apply to M/S and MH/SUD services, all services are subject to appropriate guidelines based on industry standards and generally accepted standards of medical practice and clinical appropriateness. NCS 503 otherwise does not differentiate between M/S and MH/SUD services. The relevant specific written guidelines referred to in NCS 503 are:

- **LOCUS and CALOCUS/CASII** (MH/SUD) – Aetna uses the most current versions of LOCUS and CALOCUS/CASII, which are recognized nationally as a generally accepted

standard of care tool, to guide clinicians in making medically necessary level of care determinations for mental health services. The Level of Care Utilization System (LOCUS) assessment was developed by the American Association of Community Psychiatrists (AACP) in 1996 to help determine the mental health care resource intensity needs of adults. CALOCUS was developed was developed by the American Association of Community Psychiatrists in collaboration with the American Association of Child and Adolescent Psychiatry to help determine the mental health care resource intensity needs of children and adolescents.

- **ASAM** (MH/SUD) – Aetna uses the most current criteria published by the American Society of Addiction Medicine (ASAM) to guide clinicians in evaluating the medical necessity of levels and types of care for substance use disorders. ASAM criteria are generally accepted, national standards for SUD treatment decisions and are recognized as such by many courts and regulators.

- **ABA Medical Necessity Guide** (MH/SUD) – Aetna's ABA medical necessity guidelines come from extensive review of the literature on the use of applied behavior analysis to treat autism spectrum disorder and a comparative review of the guidelines of other health insurers. A multidisciplinary committee of health care professionals within and external to Aetna Behavioral Health developed and approved the guidelines based on these reviews.

- **MCG Health Care Guidelines** (M/S) – Aetna uses the most current evidence-based care guidelines published by MCG Health to guide clinicians in making medically necessary level of care determinations for M/S services.

- **Aetna Clinical Policy Bulletins (CPBs)** (M/S and MH/SUD) – Aetna CPBs describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's medical necessity decisions regarding specific M/S and MH/SUD services.

- **NCCN Clinical Practice Guidelines in Oncology** (M/S) – Aetna uses the most current clinical practice guidelines published by the National Comprehensive Cancer Network (NCCN) to make medical necessity determinations in oncology clinical reviews. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) are comprised of recommendations for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines currently apply to more than 97% of cancers affecting patients in the United States. The NCCN Guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management.

Regarding application of state law, state amendments to NCS 503 reflect state law requirements applicable to retrospective review, including limitations on retrospective review requirements and/or the use of alternative M/S and MH/SUD medical necessity guidelines as

required by state law where applicable. Medical necessity guidelines do not replace professional judgment exercised by properly trained, licensed, and experienced clinicians and professionals who evaluate the provision of services in accordance with accepted standards of care. As explained in NCS 503, individual M/S and MH/SUD medical necessity determinations are afforded independent clinical consideration based on the member's presentation. As listed in NCS 503, staff considers the individual needs of the member when utilizing guidelines, including, but not limited to age, co-morbidities, complications, progress of treatment, need for skilled care, psychosocial situation, risk related to ethnicity or genetic factors and home environment, when applicable. Staff additionally considers the following characteristics of the local health care delivery system during the coverage determination process: the ability of the provider to meet the member's cultural and language needs, as appropriate; the availability of highly specialized services, such as detoxification facilities; the availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and, the ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition. If the UM clinician cannot approve the request, it must be forwarded to an M/S or MH/SUD medical director or consultant psychiatrist, psychologist, or BCBA-D for review. While licensed clinical staff can issue M/S and MH/SUD coverage approvals, a medical director is responsible for any M/S and MH/SUD denial of coverage, including stating and documenting the rationale for any denial. NCS 503 further notes that approval decisions may be automated when appropriate. Automation uses clinical information submitted by the provider and compares it to our clinical policies to render an approval decision, based on individualized clinical considerations, using the medical necessity guidelines outlined in NCS 503. For both M/S and MH/SUD medical necessity reviews, all adverse decisions are made by medical directors, never by automation or clinical staff who are not medical directors, as required by NCS 505: National Clinical Services Denial of Coverage Policy, discussed below. Thus, the "as written" material contained in NCS 503 pertaining to the medical review process is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

Additionally, as outlined in **NCS 527** for retrospective reviews of emergency services, Aetna clinical staff apply the federal "prudent layperson" standard to evaluate emergency claims. If an applicable state standard defines emergency care differently, the review is determined in accordance with the applicable state law definition. Additionally, Aetna considers the claim an emergency medical condition, and pays it as such, if the claim includes evidence of a referral from a physician, or evidence that an Aetna representative directed the member to an emergency room. The same criteria and process are applied for reviews of emergency services irrespective of whether the conditions at issue pursuant to the claim are M/S or MH/SUD.

NCS 504 establishes the timeliness standards for retrospective review determinations and notifications that apply equally to M/S and MH/SUD services. Attachment A to NCS 504 sets out timeliness standards for retrospective review decisions and notifications. These timeliness standards apply equally to M/S and MH/SUD inpatient, outpatient, and emergency retrospective review. Determinations for retrospective review requests are made within 30 calendar days of the request if all necessary clinical information is included with the request. Aetna will notify the requester of the determination (approval and denial) in writing within 30 calendar days of the receipt of the request. The 30-calendar day determination timeframe is an NCQA requirement. If additional information is required to make a determination, Aetna will initiate the request for additional information within 30 calendar days of the receipt of the request. These timelines apply equally to M/S and MH/SUD and are detailed in NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy (Attachment A). The timeframes and procedures set forth in NCS 504 are equally applicable to retrospective reviews for M/S and MH/SUD services and are based on the factors of NCQA accreditation standards, and applicable state and federal law. NCS 504 notes that the Aetna standard timeframes set forth above are in compliance with applicable accreditation requirements and federal law, and that state law or regulation that mandates a more stringent time supersedes the national standard.

Additionally, **NCS 505** defines and outlines the handling of denial of coverage determinations, including the responsibility for issuing clinical and administrative denial decisions, documentation requirements for denial decisions, and notification requirements for these coverage decisions. As written, this policy applies equally to M/S and MH/SUD services, which specifies that only M/S and MH/SUD medical directors can deny clinical coverage decisions.

NCS 506 outlines the peer-to-peer review process through which a treating practitioner, a clinician on behalf of the treating practitioner (e.g., genetic counselor for BRCA precertification requests) or a physician on behalf of a facility (for precertification denials) may request a discussion with a peer reviewer (licensed health plan physician medical director) or behavioral health consultant psychiatrist/psychologist/board certified behavior analyst-doctoral (BCBA-D), to discuss a clinical denial of coverage determination. Peer-to-peer is not an additional level of review or an appeal. It is a focused discussion between the provider representative and the peer reviewer. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D considers all available information when conducting a peer-to-peer review. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D reviews the applicable clinical criteria/guidelines in NCS 503, the clinical information that is present before and during the peer-to-peer discussion and uses clinical judgment to make a decision. For M/S, peer-to-peer reviews are conducted after a denial determination, upon request. For MH/SUD services, when clinically appropriate, peer-to-peer reviews are offered and conducted prior to the issuance of the initial coverage determination, in addition to peer-to-peer reviews that are available after a denial determination. As written, the process for peer-to-peer review is largely the same for M/S and

MH/SUD, except that for MH/SUD services, Aetna may offer a peer-to-peer review before a determination has been issued, in addition to the peer-to-peer review that is available post-determination. Based upon the foregoing, the written material contained in NCS 506 pertaining to peer-to-peer review is comparably applied to MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

Finally, **NCS 510** describes Aetna's Internal Quality Review and Inter-Rater Reliability assessments. As written, the IQR/IRR process provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. Through inter-rater reliability (IRR) assessments, both M/S and MH/SUD medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria, and corrective actions are taken if the results do not meet certain metrics, which are the same for M/S and MH/SUD services. The "as written" processes in NCS 510, for evaluation of medical director and utilization management clinician accuracy and consistency, are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services. The IRR results for both Behavioral Health and Medical clinicians are discussed in Step 5, and show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

The factors of 1) NCQA accreditation standards; 2) generally accepted standards of medical practice and clinical appropriateness; and 3) applicable state and federal law, are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently, as written, to MH/SUD benefits. The written policies and materials discussed herein apply to both M/S and MH/SUD benefits. Accordingly, Aetna's analysis of the "as written" material used to conduct retrospective review shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services than to M/S services.

Aetna provides members with appeal rights when an adverse benefit determination is issued. When Aetna issues a denial of services or a reduction in coverage due to an EIU determination or blanket exclusion, that determination is considered an adverse benefit determination. Members have the right to request a review of that determination through the appeal process and may initiate an appeal by contacting Aetna.

Appeal rights and procedures are described in the COC under the section titled "Appeal of an Adverse Benefit Determination." The COC outlines the appeal process, including applicable timeframes, who may request an appeal on behalf of the member, how appeals are assigned and reviewed, and the options available if the member is not satisfied with the appeal decision. Aetna does not maintain separate appeal processes for MH/SUD services and M/S services; the same appeal procedures apply to both. In addition, once the internal appeal process has been exhausted, members may have the right to request an external review, as described in the COC. The COC also explains the circumstances under which external review may be available and the procedures for

requesting it. The appeal and external review rights available to members are applied consistently for MH/SUD and M/S services and are not more stringent for MH/SUD services than for M/S services.

Summary

In sum, Aetna's analysis demonstrates that as written, the processes, strategies, evidentiary standards and other factors used in applying retrospective review to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying retrospective review to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

**The quantitative data presented in this analysis is based on Aetna Life Insurance Company (ALIC) business, which represents approximately 74% of the total Virginia business. The NQTL processes, strategies, evidentiary standards, and other factors described herein are applied consistently across the relevant Virginia business. As a result, Aetna believes the ALIC data is representative of the operational application of the NQTL and provides a reliable basis for assessing compliance with MHPAEA's comparative analysis requirements and for supporting the findings and conclusions presented in this report.*

As noted in Step 1, Part 2, Aetna conducts retrospective review of M/S and MH/SUD services for which precertification was required but was not obtained, for all OON inpatient and outpatient claims and for a limited set of INN inpatient and outpatient claims. Additionally, Aetna conducts retrospective review of emergency claims where the M/S and MH/SUD diagnosis codes submitted on an emergency department claim signify a condition that potentially was not an emergency as defined pursuant to the federal "prudent layperson" standard. Accordingly, retrospective review applies to the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient–all other; 3) out-of-network inpatient; 4) out-of-network outpatient–all other; and 5) emergency. As noted in Step 2, Part 2, different factors are applied in the context of

retrospective review for: (a) determining services subject to retrospective review – INN; (b) determining services subject to retrospective review – OON; (c) determining services subject to retrospective review – Emergency; and (d) the process of how retrospective review is performed. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying retrospective review to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying retrospective review with respect to M/S benefits.

(a) Determining services subject to retrospective review – In-network benefits (inpatient and outpatient–all other)

In operation, Aetna conducts retrospective review for M/S and MH/SUD INN inpatient services and outpatient–all other services for which precertification was required, but was not obtained, in the limited circumstances discussed herein. For outpatient–all other M/S and MH/SUD services for which precertification was required, but was not obtained, Aetna conducts retrospective review where the "additional" circumstances of state and federal law requirements and/or disaster declaration, contract requirements, or the existence of a valid reason for failure to precertify exist. These circumstances apply equally to M/S and MH/SUD services.

For inpatient M/S and MH/SUD services, Aetna conducts retrospective review, in operation, as follows: for elective and emergency M/S and MH/SUD inpatient hospital admissions for which the provider failed to obtain precertification or provide notice as required pursuant to Aetna's Timely Notification of Hospital Admissions Policy, Aetna conducts retrospective review of the same where one of the additional circumstances listed above are present. For emergency M/S and MH/SUD inpatient hospital admissions to acute medical-surgical hospitals, Aetna conducts retrospective review when Aetna is provided notice of the hospital admission, in compliance with Aetna's Timely Notification of Hospital Admissions Policy, and the member has been discharged. Aetna also conducts retrospective review of all standalone acute psychiatric hospital inpatient admissions, with no timely notification requirement. As set forth above, because conducting a retrospective review is a less stringent alternative to simply denying a claim for failure to comply with precertification or timely notification requirements, this variation represents a less, not more, stringent application of a treatment limitation with respect to MH/SUD inpatient benefits than M/S benefits.

For non-hospital inpatient admissions to facilities such as skilled nursing facilities, long-term acute care hospitals, and residential treatment centers, in operation, generally precertification is required for all such non-hospital inpatient services. Generally, if precertification is not obtained, Aetna would deny the claim for failure to satisfy precertification requirements. However, based on claim system nuances, in operation, Aetna conducts retrospective review on all RTC admissions for claims adjudicated on Aetna's EWM claim system platform regardless of whether

precertification was obtained. Similar to the instance discussed above regarding acute standalone psychiatric hospitals, because conducting a retrospective review is a less stringent alternative to simply denying a claim for failure to comply with precertification or timely notification requirements, this variation represents a less, not more, stringent application of a treatment limitation with respect to MH/SUD inpatient benefits than M/S benefits.

Thus, in operation, the processes, strategies, evidentiary standards, and other factors used to determine which MH/SUD INN services are retrospectively reviewed are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors with respect to M/S services.

(b) Determining services subject to retrospective review – Out-of-network benefits (inpatient and outpatient–all other)

In operation, Aetna conducts retrospective review on all OON M/S and MH/SUD inpatient and outpatient–all other services for which precertification is required, but was not obtained. Thus, in operation, the processes, strategies, evidentiary standards, and other factors used to determine which MH/SUD OON services are retrospectively reviewed are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors with respect to M/S services.

(c) Determining services subject to retrospective review – Emergency

For emergency services, in operation, Aetna performs retrospective review on claims for emergency services where the M/S and MH/SUD diagnosis codes signify a condition that potentially was not an "emergency" under the federal "prudent layperson" standard. If all diagnosis codes, whether M/S or MH/SUD, on a submitted emergency department claim are listed on Aetna's Non-Emergent ER Diagnosis Codes List, Aetna conducts retrospective review based on the medical records to determine whether the treatment was in fact for an emergency condition.

The chart below reflects the current Non-Emergent ER Diagnosis Codes List, including the total number of diagnosis codes that trigger a retrospective review of an emergency room claim, separated by M/S and MH/SUD, as well as the percentage of the total number of diagnosis codes on the list. MH/SUD diagnoses are identified as those in ICD-10 Chapter 5: Mental, Behavioral, and Neurodevelopmental Disorders, and M/S diagnoses are all other ICD-10 codes.

Diagnosis Codes Subject to Retrospective Review of Emergency Room Claims		
Category	**Count of Diagnosis Codes**	**Percent of Total**
M/S	1,702	94.1%

MH/SUD	106	5.9%
Total	1,810	100.0%

As set forth above, in operation, over 94% of the total codes that trigger retrospective review of emergency services pertain to M/S conditions as opposed to MH/SUD conditions. In 2025, the PPCC made a determination to add 111 new ICD-10 codes to the Non-Emergent ER Diagnosis Codes List, all of which were for M/S conditions. There were no diagnosis codes added to the list for MH/SUD conditions. The PPCC selected these codes based on its determination that these codes would not standardly be appropriate for an emergency room setting, and signify that a condition may not have been an emergency under the "prudent layperson" standard (the table above is inclusive of these additions in 2025). Thus, with respect to the emergency claims Aetna retrospectively reviews, in operation, the processes, strategies, evidentiary standards, and other factors used with respect to MH/SUD conditions are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors with respect to M/S conditions.

(d) The process of performing retrospective review

Aetna monitors the denial rates for M/S and MH/SUD retrospective review requests as one measure that can evaluate whether retrospective review is applied comparably, and not more stringently, to MH/SUD services compared to M/S services. Evaluation of this data for M/S and MH/SUD services can provide a basis to evaluate whether, in operation, the factors, evidentiary standards and sources for the retrospective review process are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits. The data below reflects the INN, OON, and emergency retrospective review decisions, and average turnaround time, for Virginia for July 2025-June 2026.

The data reflects the total number of decisions and the total number of decisions that were denied in Virginia. The data is further broken down into administrative denials and medical necessity denials. This data is retrieved from Aetna's utilization management system, in which clinicians review the medical records and document the determinations. Administrative denials are denials due to the member's lack of eligibility, the benefits for the requested services are excluded under the member's plan, the member has other coverage that is primary coverage, or the benefits have been exhausted under the member's plan. Notably, administrative denials also include denials due to not receiving clinical information necessary for decision-making, where clinical information from the provider was not provided, despite Aetna's request, to determine whether the services are considered medically necessary under the terms of the plan. Medical necessity denials are denials for which the requested service did not meet the medically necessary criteria used by clinicians during the retrospective review process.

Denial Rates (Virginia) for Retrospective Review Requests – Inpatient and Outpatient–All Other								
	In-Network Inpatient		**Out-of-Network Inpatient**		**In-Network Outpatient All Other**		**Out-of-Network Outpatient All Other**	
	M/S	**MH/SUD**	**M/S**	**MH/SUD**	**M/S**	**MH/SUD**	**M/S**	**MH/SUD**
Total Decisions	4	1	0	1	4	0	0	0
Denied Decisions	1	0	0	0	2	0	0	0
Percent Denied – Overall	**25.0%**	**0.0%**	**0.0%**	**0.0%**	**50.0%**	**0.0%**	**0.0%**	**0.0%**
Total Administrative Denials	0	0	0	0	0	0	0	0
Percent Denied - Administrative	**25.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Total Medical Necessity Denials	0	0	0	0	2	0	0	0
Percent Denied – Medical Necessity	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**50.0`%**	**0.0%**	**0.0%**	**0.0%**

The Virginia in-operation data for retrospective review requests reflects that the overall denial rate for MH/SUD services is lower than the denial rate for M/S services for the INN inpatient (0.0% for MH/SUD, compared to 25.0% for M/S) and INN outpatient-all other (0.0% for MH/SUD, compared to 50.0% for M/S) benefit classifications. No MH/SUD denials were identified for the OON inpatient or OON outpatient-all other benefit classifications, and there were either no M/S review requests or no denials in these classifications. While the percentage differences observed in certain classifications appear notable, the underlying volume of retrospective review requests is extremely small, consisting of only one MH/SUD INN inpatient request, one MH/SUD OON inpatient request, and no MH/SUD outpatient-all other requests during the review period.

Additionally, the limited number of denials identified for M/S services consisted of one denial in the INN inpatient classification and two denials in the INN outpatient-all other classification. No MH/SUD retrospective review requests were denied. Given the very low volume of retrospective review activity reflected in this data, the results do not indicate that retrospective review criteria or processes were applied more stringently to MH/SUD services than to M/S services. Accordingly, the data for INN inpatient, OON inpatient, INN outpatient-all other, and OON outpatient-all other services reflects that retrospective review is applied comparably, and not more stringently, to MH/SUD services as compared to M/S services in these benefit classifications.

The following table shows data for the emergency benefit classification, where M/S and MH/SUD claims for emergency room services are retrospectively reviewed when all diagnosis codes on the claim are on the Non-Emergent ER Diagnosis Code List. This data is retrieved from Aetna's utilization management system and includes data for the state of Virginia for July 2025 – June 2026.

Denial Rates for Virginia Retrospective Review Requests - Emergency		
	M/S	**MH/SUD**
Total Decisions	0	0
Denied Decisions	0	0
Percent Denied	**0.00%**	**0.00%**

The retrospective review denial rate for emergency M/S and MH/SUD diagnosis codes is 0.00% for the state of Virginia.

The following table shows the turnaround time (TAT) compliance rates for M/S and MH/SUD retrospective reviews for the state of Virginia. This data is retrieved from Aetna's utilization management system and shows the percentage of retrospective reviews completed within the required turnaround time. As noted in Step 4, pursuant to NCS 504: Timeliness Standards for Coverage Decisions and Notification Policy & Procedure, retrospective reviews are generally required to be completed within 30 calendar days, unless applicable state requirements prescribe a more stringent timeframe. Virginia follows Aetna's standard turnaround time requirements for retrospective reviews and does not impose a more stringent timeframe. Accordingly, retrospective review requests in Virginia are subject to the standard 30-calendar-day turnaround time requirement.

The data below is for Virginia for the timeframe of July 2025 to June 2026 and reflects the percentage of retrospective reviews completed within the required timeframe.

Virginia's Retrospective Review Turnaround Time Compliance Rates				
	Inpatient		Outpatient All Other	
	M/S	MH/SUD	M/S	MH/SUD
Percent TATs Met	75.0%	50.0%	100.0%	N/A

The retrospective review compliance rate for turnaround times reflects very limited MH/SUD review activity during the measurement period. For inpatient services, 50.0% of MH/SUD retrospective review requests were completed within the applicable turnaround time standard. While this compliance rate is lower than that observed for inpatient M/S services, the result is based on only two MH/SUD inpatient retrospective review requests during the review period, making the observed difference highly sensitive to the outcome of a single review. For the outpatient-all other benefit classification, the turnaround time compliance rate for M/S services was 100.0%, while the compliance rate for MH/SUD services is reported as N/A because no MH/SUD retrospective review requests were received during the review period.

Given the very small volume of MH/SUD retrospective review activity, the data does not support a conclusion that retrospective review turnaround time requirements were applied more stringently to MH/SUD services than to M/S services. Rather, the available data reflects that any observed differences are driven by the extremely limited number of MH/SUD requests, which were both approved. Notably, as retrospective reviews are post-service, members and providers are not awaiting response prior to delivery of care. Aetna's Quality Management Teams for both M/S and MH/SUD services continue to monitor timeliness data, evaluate trends, balance staff workloads, and identify opportunities to improve operational efficiency and maintain compliance with applicable turnaround time standards.

Additionally, the IRR process described in NCS 510: Internal Quality Review Policy & Procedure provides a way to evaluate whether utilization review of M/S and MH/SUD services is performed comparably, and not more stringently for MH/SUD, in operation. In that process, medical directors and utilization management clinicians are audited for accuracy and consistency in their application of utilization management criteria. Corrective actions are taken if the results do not meet certain individual and business unit metrics, which are the same for M/S and MH/SUD. The IRR results for both Behavioral Health and Medical clinicians and medical directors show that the audits were performed as required and the overall goals met. Overall, the final score for M/S utilization reviews was 98%. For MH/SUD, the final score was 100%. These IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services.

Summary

In sum, in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying retrospective review to MH/SUD benefits are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits in all applicable benefit

classifications. Overall, considering the aggregate denial rates for M/S and MH/SUD services across all applicable benefit classifications, average TAT, and Aetna's utilization review audits, it is reasonable to conclude that retrospective review is performed comparably, and not more stringently, with respect to MH/SUD services compared to M/S services in the applicable benefit classifications.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of §146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, retrospective review is a utilization review service performed by licensed healthcare professionals to determine coverage after an inpatient discharge or the provision of a procedure/service. The intent of the review is to determine medical necessity, appropriateness of treatment, and benefits and eligibility. Retrospective review applies to the

following benefit classifications: 1) in-network inpatient; 2) in-network outpatient–all other; 3) out-of-network inpatient; 4) out-of-network outpatient–all other; and 5) emergency.

Step 2 identified the factors considered or relied upon in the design and application of Aetna's retrospective review program, including the factors that are used to 1) determine the INN benefits subject to retrospective review; 2) determine the OON benefits subject to retrospective review; 3) determine emergency services subject to retrospective review; and 4) how the process of retrospective review is performed. Step 3 explained the evidentiary standards and sources for those factors, and how they are used in the design and application of retrospective review. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD services subject to retrospective review and concluded that there are no written differences in that application that results in any MH/SUD services being treated more stringently than, or incomparably to, M/S services. Finally, Step 5 demonstrated that, in operation, MH/SUD services are subject to retrospective review in a comparable and no more stringent manner than M/S services.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-5, Aetna applies the same factors, evidentiary standards and sources, and the same National Clinical Services Policies and Procedures to conduct retrospective review for M/S and MH/SUD services. For OON benefits, both in writing and in operation, Aetna conducts retrospective review on all OON M/S and MH/SUD inpatient and outpatient–all other services for which precertification is required, but was not obtained. For emergency services, both in writing and in operation, Aetna performs retrospective review on claims for emergency services where the M/S and MH/SUD diagnosis codes signify a condition that potentially was not an emergency under the federal "prudent layperson" standard based upon Aetna's Non-Emergent ER Diagnosis Codes List. As set forth above, in the process for determining the codes that trigger review is equally applied to M/S and MH/SUD conditions, and the vast majority (over 94%) of the total codes that trigger retrospective review of emergency services pertain to M/S conditions as opposed to MH/SUD conditions.

For INN benefits, as demonstrated above in Step 4, there are instances in which Aetna conducts retrospective review more broadly for MH/SUD acute inpatient and RTC admissions, whereas M/S hospital and non-hospital admissions are subject to denial and/or payment penalty for failure to meet precertification and timely notification requirements. These instances result in Aetna conducting retrospective review for MH/SUD services in a broader manner than for M/S services. Because conducting a retrospective review is a less stringent alternative to simply denying a claim for failure to comply with precertification or timely notification requirements, these variations represent a less, not more, stringent application of a treatment limitation with respect to MH/SUD benefits than M/S benefits.

As demonstrated in Step 5, Aetna found that the in-operation processes, strategies, evidentiary standards, and other factors used to apply retrospective review to MH/SUD benefits

demonstrate comparability to those applied to M/S benefits and are not applied more stringently. Aetna reviews in-operation denial rates for M/S and MH/SUD retrospective review requests as one measure that can assist in evaluating whether retrospective review is applied comparably, and not more stringently to MH/SUD services compared to M/S services. Aetna's in-operation data reflects an overall rate of denials that is at least comparable for MH/SUD services in all benefit classifications. In-operation data reflects no retrospective reviews for emergency MH/SUD and M/S diagnosis codes and therefore the retrospective review denial rate for both emergency MH/SUD and M/S diagnosis codes is 0%. Furthermore, retrospective review requests reflects that the overall denial rate for MH/SUD services is lower than the denial rate for M/S services for the INN inpatient (0.0% for MH/SUD, compared to 25.0% for M/S) and INN outpatient-all other (0.0% for MH/SUD, compared to 50.0% for M/S) benefit classifications. No MH/SUD denials were identified for the OON inpatient or OON outpatient-all other benefit classifications, and there were either no M/S review requests or no denials in these classifications. While the percentage differences observed in certain classifications appear notable, the underlying volume of retrospective review requests is extremely small, consisting of only one MH/SUD INN inpatient request, one MH/SUD OON inpatient request, and no MH/SUD outpatient-all other requests during the review period. Additionally, while the timeliness standards for M/S and MH/SUD retrospective review requests are the same per NCS 504, Aetna's review of turnaround time compliance rates show very limited MH/SUD review activity during the measurement period. For inpatient services, 50.0% of MH/SUD retrospective review requests were completed within the applicable turnaround time standard. While this compliance rate is lower than that observed for inpatient M/S services, the result is based on only two MH/SUD inpatient retrospective review requests during the review period, making the observed difference highly sensitive to the outcome of a single review. For the outpatient-all other benefit classification, the turnaround time compliance rate for M/S services was 100.0%, while the compliance rate for MH/SUD services is reported as N/A because no MH/SUD retrospective review requests were received during the review period.

Further, an in-operation review of the IRR results for M/S and MH/SUD show that both Medical and Behavioral Health medical directors and clinicians are performing utilization management reviews accurately and consistently overall. However, the overall results for MH/SUD are slightly higher at 100% compared to 98% for M/S.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply retrospective review to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying retrospective review to M/S benefits across the applicable benefit classifications.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Behavioral Health Medical Director, Quality and Mental Health Parity, Medical Doctor board certified in Psychiatry • Lead Director, Clinical Review Program Management • Lead Director, Business Consulting, Utilization Management Operations • Sr. Manager, Clinical Health Services, LCSW • Sr. Manager, Clinical Claim Reporting

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Nonquantitative Treatment Limitation Comparative Analysis:

"Post-Payment Retrospective Review" AKA Fraud Waste Abuse

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of the NQTL, and* ***(2)*** *an identification of all* ***in network*** *mental health/substance use disorder (MH/SUD) and medical/surgical (M/S) benefits to which the NQTL applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Fraud Waste Abuse [45 CFR 146.137(c)(1)(i)]

Aetna defines **Fraud**, Waste, and **Abuse**[I] **(FWA)** as follows:

- **Fraud:** Knowingly submitting false information to obtain money or a benefit. Examples include billing for services that were not provided or altering records to receive a higher payment.
- **Waste:** Overusing healthcare services or resources, such as conducting unnecessary office visits or prescribing more medication than is needed.
- **Abuse:** Failing to follow accepted medical or business practices, resulting in unnecessary treatments or costs—for example, billing for a brand-name drug when an appropriate generic is available.

Our FWA process identifies unusual patterns of service coding, charges, and/or other claims information are identified and analyzed to detect potential fraud, waste, or abuse. Aetna maintains a comprehensive anti-fraud program dedicated to preventing, detecting, investigating, correcting and reporting fraud, waste, and abuse. Aetna's detection and prevention protocols include fraud awareness training programs, data mining and data analytics, monitoring hotlines and other reporting mechanisms, developing relationships with law enforcement, tracking industry information on fraud, waste, and abuse trends and indictments, and promoting public awareness as the process by which unusual patterns of service coding, charges, and/or other

[I] Respectfully, Aetna disagrees that "Fraud Waste Abuse (FWA)" constitutes a non-quantitative treatment limitation, as FWA is not a "limitation that are not expressed numerically but otherwise limit the scope of duration of benefits for treatment" as contemplated by MHPAEA 45 C.F.R. § 146.136. Furthermore, FWA does not, as a strategy, target any specific benefit, provider, service or supply, and is not in any way a term of a benefit plan or coverage. Rather, the strategies to curtail fraud, waste, and abuse change or evolve over time for a variety of reasons. Aetna further objects on grounds of vagueness. Subject to and without waiving this objection, Aetna has endeavored to provide the requested information.

claims information are identified and analyzed to detect potential fraud, waste, or abuse. Aetna maintains a comprehensive anti-fraud program dedicated to preventing, detecting, investigating, correcting and reporting fraud, waste, and abuse. Aetna's detection and prevention protocols include fraud awareness training programs, data mining and data analytics, monitoring hotlines and other reporting mechanisms, developing relationships with law enforcement, tracking industry information on fraud, waste, and abuse trends and indictments, and promoting public awareness.

Aetna has a dedicated investigative unit, referred to as the Special Investigations Unit (SIU) that is responsible for preventing, detecting, investigating, correcting and reporting FWA. The unit operates separately from claim and underwriting functions. The SIU employs close to 300 colleagues, including a medical director, nurses, certified coders, former law enforcement, pharmacy technicians, attorneys, accredited healthcare fraud investigators, certified fraud examiners, program integrity managers, IT specialists, and administrative staff. Aetna's SIU includes distinct prepay and post-pay teams, dedicated to investigations, which are comprised of approximately half of Aetna's SIU.

Aetna has extensive detection and prevention protocols to combat FWA and to ensure compliance with state and federal requirements. These protocols include, but are not limited to:

- Fraud awareness training programs
- Data mining and data analytics
- Monitoring of hotlines and other reporting mechanisms
- Third-Party vendor (including PBM) referral and reporting procedures
- Developing relationships with Law Enforcement
- Tracking industry information on FWA trends and indictments
- Promoting public awareness

In addition to referrals from members, Aetna staff, and state or federal agencies, data mining rules are created and used to identify outlier claim activity for further review, which by their nature, subsequently correspond to services to which participants and beneficiaries of benefits receive. Aetna defines the FWA form of post-payment retrospective review as FWA investigations that take place both pre-payment and post-payment of a claim. In part, FWA involves reviewing paid claims to determine if a provider committed fraud, misused resources, or billed services that were not performed. We refer to this as Fraud, Waste, and Abuse; therefore, ***all services*** that correspond to possible benefits subject to 'Post Payment Retrospective Review' AKA Fraud, Waste, and Abuse, are hereby known as Fraud Waste Abuse.

The following materials describe Fraud, Waste, Abuse:

1. **Plan Documents**

There is no relevant language in Virginia's Large Group forms.

2. Provider contracts

Aetna's template provider contract for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to fraud, waste and abuse. Specifically, under "General Obligations", the template contract states, "unless prohibited by Applicable Law or a violation of a specific peer review privilege, notify Company promptly about any: … (ii) claims against Provider or a Group Provider by governmental agencies including, but not limited to, any claims regarding fraud, abuse, self-referral, false claims, or kickbacks;" The same template provider contract is used for both M/S and MH/SUD providers.

3. Facility contracts

Aetna's template provider contract for facility providers states: "General obligations. Facility agrees that it and all Facility Providers will: … unless prohibited by Applicable Law or a violation of a specific peer review privilege, notify Company promptly about any: …(ii) claims against Facility or a Facility Provider by governmental agencies including, but not limited to, any claims regarding fraud, abuse, self-referral, false claims, or kickbacks, that could reasonably have a material impact on Facility's ability to provide services to Members or to participate in Medicare or Medicaid programs" The same template provider contract is used for both M/S and MH/SUD providers.

4. Provider Manual

Fraud, Waste and Abuse is referenced in Aetna's Provider Manual, applicable to participating providers.

Prepayment reviews and post-payment audits/ reviews

A prepayment review is the process of reviewing a claim before payment is issued. During the review, medical records and other documentation are checked for medical necessity, accuracy and plan compliance. If the claim passes the review it is paid. If not, it may be denied, reduced or returned for additional information.

A post-payment audit/review is a process which claims are examined after payment has been issued to ensure the claims were properly billed and include the necessary supporting documentation. The purpose is to identify errors, including but not limited to, overpayments, fraud, waste and abuse. If errors are found, the payer may request repayment, recoupment or other penalties in accordance with applicable law.

When prepayment reviews and post-payment audits/reviews are conducted, providers are required to send us or our designee, additional documentation, including but not limited to, medical records and invoices. See below for a nonexhaustive list of prepayment reviews and post payment audits/reviews.

NOTE: This section is subject to applicable state and/or federal law.

5. Policies and procedures

The following Aetna document, which apply to M/S and MH/SUD benefits, address our Anti-Fraud Plan.

- **Health Care Anti-Fraud Plan:** This document, and the Exhibits, describes the Company's comprehensive Health Care Anti-Fraud Plan (Plan). They define the framework of our fraud prevention and detection program, and outline the standards, protocols, policies, and procedures used to prevent, detect, investigate, correct and report healthcare fraud, waste and abuse (FWA).

Step 1, Part 2. Applicable M/S and MH/SUD Benefits and Which Benefits are Included in Each Classification

Benefits and Classification

The M/S and MH/SUD services described below are included in the **in-network and out-of-network inpatient** benefit classifications, the **in-network and out-of-network outpatient office** subclassifications**,** the **in-network and out-of-network outpatient all other** subclassifications, and the **emergency** benefit classification.

Benefit classifications to which NQTL applies: ✓ INN IP ✓ INN OP AO ✓ INN OP OV ✓ OON IP ✓ OON OP AO ✓ OON OP OV ✓ Emergency	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
All M/S services can be subject to FWA	All MH/SUD services can be subject to FWA

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Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of precertification. Each subpart includes,* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to precertification, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL - Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of Fraud Waste Abuse.

Factor	Applicable to M/S	Applicable to MH/SUD
Data Mining Rules	✓	✓

- **Data Mining Rules** is a factor and strategy supporting identifying Fraud Waste and Abuse for M/S and MH/SUD benefits. The list below identifies data mining rules that in some circumstances correspond to benefits that had suspect claims and/or billing issues within the review period warranting inquiry in the interest of preventing fraud, waste, and abuse. These are developed and refined based on a combination of historical claims data, emerging industry trends, evolving fraud schemes, regulatory guidance, investigative outcomes, and subject matter expertise. The specific analytic methodologies, algorithms, thresholds, and detection criteria utilized by SIU are proprietary and are evaluated to maintain effectiveness in identifying potentially suspicious billing activity.

This list is subject to naturally change based on the factors and standards discussed more fully in later steps below.

Medical Surgical	MH/SUD
• UV Light Home Services Not Rendered • MODEL: Genomics FWA Model • Consecutive COVID Testing • HIV Spike • Par Providers Billing as Non-Par	• Consecutive PHP or IOP for Members Out of State – BH • X Plan Sponsor- BH • Recovery Treatment Facility/Substance Abuse Facility stay with outpatient services billed

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• Providers Billing High Percentage of Compromised Members • Continuous Glucose Monitors (CGMs) • Allergy Self-Injecting Members • Ansar (Autonomic Testing) • Extremity U/S Complete - Other than Podiatrist • Massage • Inclusive in Primary PX • Prolonged Services • Unlisted Misc. Codes • Unlisted Labs • Active Cold Compression Devices • Emergency Add-on • Unlisted E&M • Unlisted Ophthalmology Codes • Upcoding of High Level Home Visits_ • Colon Cleansing • Esophagogastroduodenoscopy • Intraoperative Monitoring (IOM) • DME Network Analysis • Lab Codes billed > 20 Units • Convenience Medical Kits • Allergy Svcs by Non-Allergy Providers • Functional/Regenerative Medicine • Claim Volume Spike Analysis • Model: Suspect Provider Demographics • Genetic Testing • Lactation Consultants Double Billing services for Mom and Baby • High Level Office Visits billed with Telehealth Modifier • COVID Drive Through • I/E Nerve Blocks and Treatments • SCOUT • MODEL: High Risk Non-Par Providers • Out of Scope Billing for Chiropractic Services • CLIA - No CLIA Certificate • Plan Sponsor Overutilization • At Home COVID Test Kits • Multiple Providers at Common Address Report (DME / LAB) • DBAR Preclusion Lists • DMR Direct Member Reimbursement - excluding BH • Urinary Catheters DME Spike • Potential Phantom Labs • Members Enrolled Utilizing the Same PII Information • Remote Patient Monitoring (RPM) • DME Peer Model • Anesthesia Peer Model • Infectious Disease	• High frequency E/Ms billed with Psychotherapy • QEEG, Brain Mapping and Neurofeedback • Direct Member Reimbursement (DMR) • Spravato / Esketamine Double Billing • Patient Brokering • Infusion Centers Billing IV Ketamine Therapy With BH dx • Interactive Complexity • High Level EM billed with Psychotherapy • IOP Weekly Bundle • Behavioral Health Peer Model • TMS+ Ketamine • Targeted Case Mgmt and Community-Based Services • Improbable Hours-ABA • Consecutive Days of Psychotherapy Services • Neuropsych Testing • Medically Unnecessary Psychiatric Evaluations • Psychosocial Rehab • TBOS Billing Shift Prevention • Misrepresentation-PHP • Improbable BH Services • Vivitrol

• HFPP Healthcare Fraud Prevention Partnership Alert • Pneumatic Compression Appliances • Amniotic Membrane Patches and Skin Substitutes • RFI Data Mining • Trauma Activation • DMR Service Operations Exclusion • Inappropriate Billing of PLA Codes • Amniotic Membrane and Skin Substitute Grafts • Multiple POS Same Day Billing	

The **evidentiary standards and sources** upon which this factor is based are:

- **Historical claims data:** Patterns in prior claims, including utilization frequency, billing volume, code combinations, units billed, place of service, provider specialty, member overlap, and peer-group variation, are analyzed to identify statistically unusual or inconsistent activity. Confirmed or recurring anomalies may support the creation or refinement of a data mining rule designed to flag comparable claims for further review. A statistical outlier or rule match is an indicator for inquiry and does not, by itself, establish fraud, waste, or abuse.
- **Emerging industry trends:** Information concerning new technologies, treatment settings, coding practices, reimbursement patterns, and shifts in utilization across the health care industry is evaluated to identify areas where atypical billing may emerge. Trends observed across payers or provider types may be used to develop prospective rules or adjust existing rules so that detection methods remain responsive to changes in health care delivery and billing.
- **Evolving fraud schemes:** Newly identified or changing schemes—such as billing for services not rendered, upcoding, unbundling, duplicate billing, misrepresentation of non-covered services, patient brokering, identity misuse, or manipulation of provider and place-of-service information—are assessed for recognizable claims indicators. Those indicators may be translated into data mining logic that identifies similar patterns for investigation while allowing rules to be revised as schemes change.
- **Regulatory guidance:** Applicable federal and state laws, regulations, agency guidance, coding requirements, program-integrity publications, enforcement notices, and fraud alerts are reviewed to identify compliance expectations and recognized areas of vulnerability. Data mining rules may be designed or modified to detect billing patterns associated with those identified risks and are evaluated for consistency with applicable legal, contractual, and benefit requirements.
- **Investigative outcomes:** Results of completed and ongoing investigations—including substantiated findings, unsubstantiated referrals, provider explanations, medical-record reviews, coding validation, overpayment recoveries, and referrals to regulatory or law-enforcement entities—are used to evaluate rule effectiveness. These outcomes help

refine rule logic, thresholds, exclusions, and prioritization to improve the identification of potentially suspicious activity and reduce unnecessary review of legitimate claims.

- **Subject matter expertise:** SIU investigators, clinicians, certified coders, data analysts, program-integrity professionals, legal and compliance personnel, and other qualified specialists contribute knowledge regarding accepted clinical practice, coding conventions, provider operations, fraud indicators, and investigative experience. Their input supports the selection of relevant data elements, interpretation of anomalies, validation of rule concepts, and periodic review of whether rules remain accurate, appropriate, and comparably applicable to M/S and MH/SUD claims.
-

Step 2, Part 2. Application of the NQTL - Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137 (c)(2)(i)(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) determining services subject to Fraud Waste Abuse; and (b) the process of creating data mining rules for Fraud Waste Abuse prevention.

The primary overarching factor in determining if Fraud Waste Abuse management will apply to M/S and MH/SUD services is whether review and management is necessary to prevent, detect and investigate potential FWA.

Factor	Applicable to M/S	Applicable to MH/SUD
Billing for services not rendered:	□	□
Upcoding	□	□
Unbundling	□	□
Performing medically unnecessary services or misrepresenting non covered treatments	□	□

The following **factors** were used to identify applicable data mining rules listed in Step 2, Part 1.

- **Billing for services not rendered** refers to billing patterns potentially indicative of billing for services not rendered, whether the entire claim is fabricated or an otherwise legitimate claim is padded with charges for services that did not take place. This is both a factor and a strategy. The **evidentiary standards and sources** upon which this factor is based is the lack of the expected related service. These types of claims may be referred from members or Aetna customer service when a member receives an explanation of

benefits from a provider they did not see or for services they did not receive.

- **Upcoding** refers to billing for more expensive services than what was actually performed. The **evidentiary standards and sources** upon which this factor is based are the same as the Unbundling factor below.
- **Unbundling** refers to billing for each step of a procedure as if they are separate procedures. The **evidentiary standards and sources** upon which this factor is based are HCPCS and NCCI coding guidelines.
    - **Coding methodology** helps ensure correct billing and reimbursement for the services actually performed. For providers to submit claims, medical coders translate diagnoses, procedures, and treatments into alphanumeric codes used on claims. These code sets have specific requirements for correct and compliant coding. Aetna validates claim coding and reviews medical records to accurately reimburse for services rendered to members.
    - **Healthcare Common Procedure Coding System (HCPCS) Level I:** The American Medical Association (AMA) standardized the Current Procedural Terminology (CPT®) code sets to report procedures and services typically furnished by physicians and other health care professionals. CPT codes comprise HCPCS Level I. The AMA also provides CPT® coding guidelines that detail when and how to assign codes, which codes can and can't be reported together, and other factors critical to compliant coding. The AMA updates the CPT® code set annually, releasing new, revised, and deleted codes, as well as changes to CPT® coding guidelines.
    - **Healthcare Common Procedure Coding System (HCPCS) Level II:** The Centers for Medicare and Medicaid Services (CMS) maintains Healthcare Common Procedure Coding System (HCPCS) Level II codes, which represent services, supplies, and equipment not identified by CPT® codes. HCPCS Level II codes are part of the regulation to implement the Health Insurance Portability and Accountability Act (HIPAA), which includes a requirement for standardized coding systems.
    - **National Correct Coding Initiative (NCCI)** edit guidelines are maintained by CMS. NCCI edits include Procedure to Procedure (PTP) edits, Medically Unlikely Edits (MUE), and Add-on Code edits. Most NCCI edits only apply to Medical/Surgical services. Aetna follows the NCCI coding policy for psychiatric services, detailed in Chapter 11, Section C. For example, diagnostic and therapeutic psychiatric services should not be reported on the same date of service. When billed together, only the diagnostic service is reimbursed.

- **Performing medically unnecessary services or misrepresenting non-covered treatments** refers to providers performing medically unnecessary services or misrepresenting non-covered treatments as medically necessary, covered, treatments.

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The **evidentiary standards and sources** upon which this factor is based are Aetna's Clinical Policy Bulletins and Payment Policies. Performing medically unnecessary services means offering services patients do not need for the purpose of generating insurance payments. Misrepresenting non-covered treatments means using CPT codes for covered services to obtain insurance payment for experimental or excluded services, whereas the claim would be denied if it were accurately coded.

All factors are the same for Med/Surg and MH/SUD. Data mining rules could be implemented for M/S and MH/SUD services if a pattern or scheme is identified. No factor is given more weight than any other factor.

Step 3: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: (1) design and (2) application. Each subpart includes an explanation of: (a) how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL, (b) the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL, (c) if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and (d) as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.

Step 3, Part 1. Design of the NQTL: How Factors are Used [45 CFR 146.137(c)(3)]

- **Data mining rules** is a factor and strategy supporting Aetna's Fraud Waste Abuse process.

(a) How the factor is used to determine which benefits are subject to the NQTL: The data mining rule factor applies the same to both all M/S and MH/SUD benefits and is one factor underlying Aetna's Special Investigation Unit (SIU) anti-fraud health care plan.

The SIU reviews historical claims data, emerging industry trends, evolving fraud schemes, regulatory guidance, investigative outcomes, and subject matter expertise to determine the data mining rules put in place to prevent Fraud Waste and Abuse. SIU is a multidisciplinary committee comprising of a medical director, nurses, certified coders, former law enforcement, pharmacy technicians, attorneys, accredited healthcare fraud investigators, certified fraud examiners, program integrity managers, IT specialists, and administrative staff.

Additionally, SIU's Health Care Anti-Fraud Plan: This document, and the Exhibits, describes the Company's comprehensive Health Care Anti-Fraud Plan (Plan). They define the framework of our fraud prevention and detection program, and outline the standards, protocols, policies, and procedures used to prevent, detect, investigate, correct and report healthcare fraud, waste and abuse (FWA).

(b) Explanation of the evidentiary standards considered or relied upon in designing the NQTL: The evidentiary standards relied upon when designing this NQTL are

1. **Historical claims data:** Patterns in prior claims, including utilization frequency, billing volume, code combinations, units billed, place of service, provider specialty, member overlap, and peer-group variation, are analyzed to identify statistically unusual

or inconsistent activity. Confirmed or recurring anomalies may support the creation or refinement of a data mining rule designed to flag comparable claims for further review. A statistical outlier or rule match is an indicator for inquiry and does not, by itself, establish fraud, waste, or abuse.

2. **Emerging industry trends:** Information concerning new technologies, treatment settings, coding practices, reimbursement patterns, and shifts in utilization across the health care industry is evaluated to identify areas where atypical billing may emerge. Trends observed across payers or provider types may be used to develop prospective rules or adjust existing rules so that detection methods remain responsive to changes in health care delivery and billing.
3. **Evolving fraud schemes:** Newly identified or changing schemes—such as billing for services not rendered, upcoding, unbundling, duplicate billing, misrepresentation of non-covered services, patient brokering, identity misuse, or manipulation of provider and place-of-service information—are assessed for recognizable claims indicators. Those indicators may be translated into data mining logic that identifies similar patterns for investigation while allowing rules to be revised as schemes change.
4. **Regulatory guidance:** Applicable federal and state laws, regulations, agency guidance, coding requirements, program-integrity publications, enforcement notices, and fraud alerts are reviewed to identify compliance expectations and recognized areas of vulnerability. Data mining rules may be designed or modified to detect billing patterns associated with those identified risks and are evaluated for consistency with applicable legal, contractual, and benefit requirements.
5. **Investigative outcomes:** Results of completed and ongoing investigations—including substantiated findings, unsubstantiated referrals, provider explanations, medical-record reviews, coding validation, overpayment recoveries, and referrals to regulatory or law-enforcement entities—are used to evaluate rule effectiveness. These outcomes help refine rule logic, thresholds, exclusions, and prioritization to improve the identification of potentially suspicious activity and reduce unnecessary review of legitimate claims.
6. **Subject matter expertise:** SIU investigators, clinicians, certified coders, data analysts, program-integrity professionals, legal and compliance personnel, and other qualified specialists contribute knowledge regarding accepted clinical practice, coding conventions, provider operations, fraud indicators, and investigative experience. Their input supports the selection of relevant data elements, interpretation of anomalies, validation of rule concepts, and periodic review of whether rules remain accurate, appropriate, and comparably applicable to M/S and MH/SUD claims.

(c) If the factor depends on specific decisions made in the administration of benefits: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) Deviations or variations from a factor: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factor of data mining rules apply equally and agnostically to both M/S and MH/SUD benefits in the general design of Fraud Waste and Abuse. Because this NQTL is based on a single factor, there is no ordering, hierarchy, or weighting of factors in its design of this NQTL. This factor is applied consistently across both benefit classifications to support the identification and review of potential fraud, waste, and abuse activities.

Step 3, Part 2. Application of the NQTL - How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in developing the Data Mining Rules in application of preventing Fraud Waste Abuse.

- **Billing for services not rendered** which refers to billing patterns potentially indicative of billing for services not rendered, whether the entire claim is fabricated or an otherwise legitimate claim is padded with charges for services that did not take place. This is both a factor and a strategy.
    - ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. As described below, FWA is used when billing patterns are indicative of billing for services not rendered.
    - ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: This factor is based is the lack of the expected related service. These types of claims may be referred from members or Aetna customer service when a member receives an explanation of benefits from a provider they did not see or for services they did not receive.
    - ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
    - ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Upcoding** refers to billing for more expensive services than what was actually performed.
    - ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. FWA is used when billing patterns occur for more expensive services than actually performed.
    - ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: This factor is based is evidentiary standards described in the Unbundling factor below.

- ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
- ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Unbundling** refers to billing for each step of a procedure as if they are separate procedures.
  - ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. FWA is used when billing patterns occur for more expensive services than actually performed.
  - ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: This factor is based on the evidentiary standards described as:
    - **Coding methodology** helps ensure correct billing and reimbursement for the services actually performed. For providers to submit claims, medical coders translate diagnoses, procedures, and treatments into alphanumeric codes used on claims. These code sets have specific requirements for correct and compliant coding. Aetna validates claim coding and reviews medical records to accurately reimburse for services rendered to members.
    - **Healthcare Common Procedure Coding System (HCPCS) Level I:** The American Medical Association (AMA) standardized the Current Procedural Terminology (CPT®) code sets to report procedures and services typically furnished by physicians and other health care professionals. CPT codes comprise HCPCS Level I. The AMA also provides CPT® coding guidelines that detail when and how to assign codes, which codes can and can't be reported together, and other factors critical to compliant coding. The AMA updates the CPT® code set annually, releasing new, revised, and deleted codes, as well as changes to CPT® coding guidelines.
    - **Healthcare Common Procedure Coding System (HCPCS) Level II:** The Centers for Medicare and Medicaid Services (CMS) maintains Healthcare Common Procedure Coding System (HCPCS) Level II codes, which represent services, supplies, and equipment not identified by CPT® codes. HCPCS Level II codes are part of the regulation to implement the Health Insurance Portability and Accountability Act (HIPAA), which includes a requirement for standardized coding systems.
    - **National Correct Coding Initiative (NCCI)** edit guidelines are maintained by CMS. NCCI edits include Procedure to Procedure (PTP) edits, Medically Unlikely Edits (MUE), and Add-on Code edits. Most NCCI edits only apply

to Medical/Surgical services. Aetna follows the NCCI coding policy for psychiatric services, detailed in Chapter 11, Section C. For example, diagnostic and therapeutic psychiatric services should not be reported on the same date of service. When billed together, only the diagnostic service is reimbursed.

- ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
- ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Performing medically unnecessary services or misrepresenting non-covered treatments** refers to providers performing medically unnecessary services or a misrepresentation of non-covered treatments as medically necessary, covered, treatments.

  - ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. FWA is used when medically unnecessary are performed or misrepresentation of non-covered treatments as medically necessary, covered, treatments.
  - ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: This factor is based on Aetna's Clinical Policy Bulletins and Payment Policies. Performing medically unnecessary services means offering services patients do not need for the purpose of generating insurance payments. Misrepresenting non-covered treatments means using CPT codes for covered services to obtain insurance payment for experimental or excluded services, whereas the claim would be denied if it were accurately coded.
  - ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
  - ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4]

*This Step 4 demonstrates that, under the terms of the plan, **as written**, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts: **(1)** design and **(2)** application. Within each such discussion, this Step 4 addresses **(a)** documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification, **(b)** in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL, **(c)** documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and **(d)** as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Aetna maintains a comprehensive anti-fraud program dedicated to preventing, detecting, investigating, correcting and reporting fraud, waste, and abuse. Aetna's detection and prevention protocols include fraud awareness training programs, data mining and data analytics, monitoring hotlines and other reporting mechanisms, developing relationships with law enforcement, tracking industry information on fraud, waste, and abuse trends and indictments, and promoting public awareness.

All written materials used in establishing and conducting Fraud Waste Abuse for MH/SUD and M/S are the same. Aetna's Special Investigations Unit (SIU) Anti-Fraud Plan describes Aetna's comprehensive Health Care Anti-Fraud Plan, including the framework of the fraud prevention and detection program, and outlines the standards, protocols, policies, and procedures used to prevent, detect, investigate, correct and report healthcare fraud, waste and abuse (FWA). FWA applies to the following benefit classifications: the in-network and out-of-network inpatient benefit classifications, the in-network and out-of-network outpatient office subclassifications, the in-network and out-of-network outpatient all other subclassifications, and the emergency benefit classification.

As noted in Step 2, Part 1, the factor used in the design of FWA is data mining rules. This general design factor is the basis and rationale underlying Aetna's policies and processes related to FWA.. This design factor does not distinguish between, and is applied the same to, both M/S and MH/SUD benefits. Thus, as written, the written processes, strategies, evidentiary standards and other factors used to apply Fraud Waste Abuse to MH/SUD benefits demonstrate

comparability to those applied to M/S benefits and are not applied more stringently.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, FWA apply to the following benefit classifications: in-network and out-of-network inpatient benefit classifications, the in-network and out-of-network outpatient office subclassifications, the in-network and out-of-network outpatient all other subclassifications, and the emergency benefit classification.

As set forth above, Aetna applies the FWA data mining rule process to any M/S and MH/SUD services. As noted in Step 2, Part 2, different factors are relied upon in the application of the NQTL for: (a) determining data mining rules subject to Fraud Waste Abuse; and (b) the process of performing Fraud Waste Abuse. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying FWA to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying FWA requirements to M/S benefits in the applicable benefit classifications.

Determining the services subject to the FWA and the creation of a data mining rule As noted in Step 2, Part 2, the factors used in (a) determining services subject to Fraud Waste Abuse; and (b) the process of creating data mining rules for Fraud Waste Abuse prevention.

(a) As set forth above in Step 2, Part 2, the primary overarching factor in determining if Fraud Waste Abuse management will apply to M/S and MH/SUD services is whether review and management is necessary to prevent, detect and investigate potential FWA.

(b) As set forth above in Step 2, Part 2, the factors used in application, for the process of creating data mining rules are: **Billing for services not rendered** which refers to billing patterns potentially indicative of billing for services not rendered, whether the entire claim is fabricated or an otherwise legitimate claim is padded with charges for services that did not take place, and **Upcoding** which refers to billing for more expensive services than what was actually performed, and, **Unbundling** which refers to billing for each step of a procedure as if they are separate procedures, and, **Performing medically unnecessary services or misrepresenting non-covered treatments** which refers to providers performing medically unnecessary services or misrepresenting non-covered treatments as medically necessary, covered, treatments.

In sum, Aetna's analysis demonstrates that as written, the processes, strategies, evidentiary standards, and other factors used in applying treatment plan requirements to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying treatment plan requirements to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

Aetna's analysis of the "in operation" procedures in place to review and manage outliers shows that those strategies are applied comparably to M/S and MH/SUD services and not more stringently designed or applied to MH/SUD services than to M/S services.

Aetna's Special Investigations Unit may identify outliers both pre-payment and post-payment. When SIU determines that a closer review of a provider's claims is required because a potential for health care fraud, waste, or abuse has been identified, Aetna may take the following actions:

- Flag the provider in the provider database to route claims for review prior to payment. This can include a review of medical records prior to payment, as described above, or can deny claims (for example, if a provider submits claims for services after their license has been suspended or revoked).
- Terminate the provider's contract if they were participating.
- Recover overpaid claims.
- Referrals to state/federal agencies, if appropriate.
-

A review of the SIU cases opened during 07/01/2025-06/30/2026 reporting period for Virginia's fully insured commercial book of business shows that 0% of the cases were for MH/SUD providers, compared to 100% for M/S providers. This shows that MH/SUD providers are not targeted for Fraud Waste Abuse more frequently than M/S providers.

	Medical/Surgical	MH/SUD
Count of cases opened	1	0
Percentage of cases	**100%**	**0%**

In sum, based upon review of the data and information addressed herein, the factors, evidentiary standards and sources for establishing the Fraud Waste Abuse process, are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits in operation. Based on the data and reviews discussed above, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying Fraud Waste Abuse to MH/SUD benefits are comparable to, and applied no more

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stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying Fraud Waste Abuse with respect to M/S benefits in the applicable benefit applications.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

Aetna is committed to compliance with all federal and state laws, rules, and regulations, implementing effective fraud, waste, and abuse detection and prevention controls, and investigating potential fraud, waste, and abuse. Aetna's process for reviewing outliers for MH/SUD claims and providers is similar to, and not more stringent than, the process for reviewing M/S outlier claims and providers.

As demonstrated in ***Step 1***, all M/S and MH/SUDs services that correspond to possible benefits are subject to Fraud Waste Abuse. ***Step 2*** identified data mining rules that in some circumstances correspond to benefits that had suspect claims and/or billing issues within the review period warranting inquiry in the interest of preventing fraud, waste, and abuse As demonstrated in Step 2, the same process is used to develop those rules for both MH/SUD and M/S services, and that process relies on the same types of criteria for both benefit types. ***Step 3*** explained in detail the evidentiary standards and sources. The source is the same for both M/S and MH/SUD - based on correct coding as defined by the AMA and CMS, as well as medical necessity based on Aetna's CPBs. In totality, although the same factors could be used to identify additional MH/SUD benefits subject to Fraud Waste Abuse, as set forth above 24 MH/SUD benefit patterns were subject to Fraud Waste Abuse, as compared to 60 categories of M/S benefit patterns subjected to Fraud Waste Abuse. There is not a factor, source or evidentiary standard that is relied on solely for M/S or MH/SUD; they are used and applied comparably across benefit types. ***Step 4*** then explained how those factors are applied, in writing, to M/S and MH/SUD services. Notably,

Aetna's Special Investigations Unit (SIU) Anti-Fraud Plan describes Aetna's comprehensive Health Care Anti-Fraud Plan, including the framework of the fraud prevention and detection program, and outlines the standards, protocols, policies, and procedures used to prevent, detect, investigate, correct and report healthcare fraud, waste and abuse (FWA). Aetna uses the same written SIU Anti-Fraud Plan for both M/S and MH/SUD investigations. Finally, ***Step 5*** demonstrated that, in operation, the steps taken to investigate outliers, flag or terminate providers if necessary, and recover overpaid claims are the same for both M/S and MH/SUD providers. The outcome data for our Virginia fully insured commercial book of business during the reporting period shows that there were fewer cases for MH/SUD providers than for M/S providers.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4).

Analysis completed:	September 18, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Sr. Manager, Mental Health Parity Team

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Nonquantitative Treatment Limitation Comparative Analysis:

TREATMENT PLANS

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of the NQTL, and* ***(2)*** *an identification of all mental health or substance use disorder (MH/SUD) and medical or surgical (M/S) benefits to which a treatment plan requirement applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Treatment Plan [45 CFR 146.137(c)(1)(i)]

A treatment plan is an individualized plan of care where: objective measures of baseline levels are recorded; specific goals are clearly defined; and quantifiable criteria for progress are established. Certain M/S and MH/SUD services (detailed below) require a written treatment plan as part of a medical necessity review, which may take place in the context of precertification or retrospective review.[1] Specifically, one MH/SUD service, and two M/S services are subject to a treatment plan requirement as set forth herein. The following materials describe treatment plan requirements as a component of medical necessity for the specific applicable M/S and MH/SUD services detailed below:

1. **Plan Documents**

The member's certificate of coverage defines medical necessity. Virginia's standard certificate of coverage provides:

Certificate of Coverage – AL HCOC 14

Providing covered services

Your plan provides **covered services**. These are: **…**

- **Medically necessary**. See the [*How your plan works – Medical necessity [and precertification] requirements*] [*How your plan works – Medical necessity[, referral, and, precertification] requirements*] section and the *Glossary* for more information.

Medical necessity[, referral, and, precertification] requirements

Medically necessary, medical necessity

[1] Insured plans in a state that mandates a different definition of medical necessity and/or requires use of specific medical necessity guidelines are administered in accordance with the state's requirements.

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

Medically necessary, medical necessity

Covered services under the plan must be **medically necessary**. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**." That is where we also explain what our medical directors or a **[physician]** they assign consider when determining if a service is **medically necessary**.

Glossary Definition

Medically necessary, medical necessity (mental health or substance use disorder)

A service or product addressing the specific needs of a patient for the purpose of screening, preventing, diagnosing, managing, or treating such disorder, including:

- Minimizing the progression of such disorder, in a manner that is in accordance with generally accepted standards of mental health or substance use disorder care
- Clinically appropriate in terms of type, frequency, extent, site, and duration
- Not defined primarily for the economic benefit of an insurer or purchaser or for the convenience of the patient, treating physician, or other health care provider.

Generally accepted standards of mental health or substance use disorder care means evidence-based independent standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment. Sources reflecting "generally accepted standards of mental health or substance use disorder care" include:

- Peer-reviewed scientific studies and medical literature
- Consensus guidelines and recommendations of nonprofit health care provider professional associations and specialty societies
- Nationally recognized clinical practice guidelines, including:
  - Patient placement criteria
  - Service intensity assessment instruments
  - Clinical practice guidelines
  - Guidelines and recommendations of federal government agencies
  - Drug labeling approved by the U.S. Food and Drug Administration

Important note:

We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

Medically necessary, medical necessity (other than mental health or substance use disorder)

Health care services or supplies that prevent, evaluate, diagnose or treat an illness, injury, disease or its symptoms, and that are all of the following, as determined by us within our discretion:

- In accordance with "generally accepted standards of medical practice"
- Clinically appropriate, in terms of type, frequency, extent, duration, and considered effective for your illness, injury or disease
- Not primarily for your convenience, the convenience of your **[physician]**, or other health care **[provider]**
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your illness, injury or disease

Generally accepted standards of medical practice mean:

- Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and
- Following the standards set forth in our clinical policies and applying clinical judgment

Important note:

We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

2. Provider Contracts

Aetna's template provider agreement for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to medical necessity. The same template provider contract is used for both M/S and MH/SUD providers. The agreement provides "Provider agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Provider agrees to comply with Company Policies, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria; Provider Manuals; clinical policy bulletins; credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, complaint and appeals, and other policies and procedures (as modified from time to time), that are made available to Provider electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

3. Facility Contracts

In addition, Aetna's template provider contract for facility providers sets forth the obligations of Aetna's participating facilities, relating to medical necessity. The same template contract is used for both M/S and MH/SUD providers. The contract provides "Facility agrees to provide Company and Payers with the information and records necessary for them to properly administer claims and the applicable Plan" and "Facility agrees to comply with Company Policies of which Facility knows or reasonably should have known, including, but not limited to, those contained in the Provider Manual, as modified by Company from time to time." Under "Definitions," the template contract states:

> Policies. Company's policies and procedures that relate to this Agreement, including, but not limited to, Participation Criteria, Provider Manuals, clinical policy bulletins, credentialing/recredentialing, utilization management, quality management, audit, coordination of benefits, Institutes of Excellence™, complaint and appeals, and other policies and procedures (as modified from time to time) that are made available to Facility electronically or through other commonly accepted media. Policies may vary by Affiliate, Product Category and/or Plan.

Additionally, under "Facility Obligations," the template contract states:

> Utilization Management. Facility agrees that it shall be subject to utilization management (including prospective, concurrent and retrospective review) and that payment for Facility services may be adjusted or denied for the inefficient delivery of services related to admissions, or length of stay. To facilitate timely and accurate concurrent utilization management, Facility and Company will cooperate as necessary to facilitate on-site and/or concurrent telephonic utilization management at Facility.

Precertification and Referrals. Except when a Member requires emergency services, Facility agrees to comply with any applicable precertification and/or referral requirements under the Member's Plan prior to the provision of Facility services. Facility will utilize the electronic real time HIPAA compliant transactions, including but not limited to, eligibility, precertification and claim status inquiry transactions. Facility agrees to provide notice of all admissions of Members, and of all services for which Company requires notice, upon admission or prior to the provision of such services. For the purpose of pre-admission testing, Facility agrees to directly provide testing or accept test results and examinations performed outside Facility, provided such tests and examinations are: (a) performed by a state licensed laboratory for laboratory tests, and a licensed physician for such other tests and examinations; and (b) performed within a time reasonably proximate to the admission. For those Members who require services under a specialty program, Facility agrees to work with Company in transferring the Member's care to a specialty program Facility, as the case may be.

4. Provider Manual

Applicable treatment plan requirements are a component of medical necessity. Medical necessity requirements are referenced in Aetna's Provider Manual, applicable to participating providers. The provider manual excerpts related to medical necessity, and by extension, treatment plan requirements are in Appendix A.

5. Policies and Procedures

The following internal Aetna policies, which apply to M/S and MH/SUD benefits, address medical necessity, of which treatment plan requirements are a component:

- **NCS 503: Medical Review Policy and Procedure** defines the clinical criteria/guidelines used for medical reviews, describes the procedure for application of the clinical criteria in medical necessity reviews and decision making, and references associated P&Ps related to decision and notification procedures.
  - **National Clinical Services (NCS) 503 Medical Review – Virginia**
    - This amendment is written to meet regulatory and statutory requirements under Virginia Code §38.2-3418.17 that impact the NCS 503, Medical Review Policy and Procedure. This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
  - **NCS 505: Denial of Coverage Policy and Notification** – Aetna policy defining and outlining the handling of denial of coverage determinations.
    - **National Clinical Services NCS 505: Denial of Coverage Policy and Notification – Virginia**

        - This amendment is written to meet regulatory and statutory requirements under Virginia law/regulation that impacts NCS 505, Denial of Coverage policy and procedure. This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements.
- **NCS 506: Peer-to-Peer Review Policy** – Aetna policy that describes the process for treating practitioners/clinicians/physicians to discuss a clinical denial with a peer reviewer or behavioral health consultant/psychiatrist/psychologist.
    - **National Clinical Services NCS 506: Peer-to-Peer Review – Virginia**
        - This Amendment is written to meet regulatory and legislative requirements under Virginia law/regulation that impacts NCS 506, Peer to Peer Review policy and procedure. This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.

Additionally, Aetna's Care Management Program Description (**"UM Program Description"**) encompasses Aetna's utilization management program. The UM Program Description supports Aetna's medical necessity review processes and details the accountability and structure of the committees responsible for reviewing, updating, and adopting the clinical criteria used in medical necessity reviews and the policies and procedures for applying clinical criteria.

6. Medical Necessity Criteria

Medical necessity criteria reflecting written treatment plan requirements are listed below:

Service	Link	Benefit Type
Applied behavior analysis	aetna.com/content/dam/aetna/pdfs/health-care-professionals/applied-behavior-analysis-guide.pdf	MH/SUD
Hyperbaric oxygen therapy	aetna.com/cpb/medical/data/100_199/0172.html	M/S
Skilled private duty nursing	aetna.com/cpb/medical/data/100_199/0136.html	M/S

* None of the services associated with the treatment plan require precertification. As a result, treatment plans are not reviewed or required as part of the prior authorization, concurrent review, or retrospective review processes and do not affect precertification determinations. We will review for medical necessity.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Benefits and Classification

Treatment plan requirements apply to M/S and MH/SUD benefits in the following benefit classifications, as set forth below: **in-network outpatient–all other** and **out-of-network outpatient–all other**.

Benefit Classifications to which NQTL Applies: ✔ **INN OP AO** ✔ **OON OP AO**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
▪ Hyperbaric oxygen therapy[2] ▪ Skilled private duty nursing	▪ Applied behavior analysis (ABA)

[2] Applies to in-network only

<u>Step 2</u>: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: (1) design, and (2) application of treatment plan requirements. Each subpart includes:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to a treatment plan requirement, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL:

Factor	Applicable to M/S	Applicable to MH/SUD
Quality care and service to members	✓	✓
Accordance with generally accepted standards of medical practice	✓	✓
Cost management	✓	✓

- **Quality care and service to members** is a **factor** and strategy supporting Aetna's medical necessity processes for M/S and MH/SUD benefits, to facilitate quality care and service to members. The **evidentiary standards** and **sources** upon which this factor is based are:
    - National Committee for Quality Assurance Standards and Guidelines for the Accreditation of Health Plans and National Committee for Quality Assurance Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Utilization Management ("NCQA UM" and "NCQA MBHO UM"). The source for these evidentiary standards is NCQA, an accrediting body providing guidance on utilization review programs, including the selection and application of medical necessity guidelines, as implemented through Aetna's UM Program Description.

- **Accordance with generally accepted standards of care**, means, pursuant to Virginia certificate of coverage, standards based on credible scientific evidence published in peer-reviewed medical literature and generally recognized by the relevant medical community. The **evidentiary standards and sources** upon which this factor is based are:
    - Peer-reviewed published medical literature, including literature indexed in the National Library of Medicine PubMed Database.
    - In general, Aetna Clinical Policy Bulletins contain the evidentiary standards (i.e., clinical treatment guidelines) that are used in the design of this NQTL to support the factor of accordance with generally accepted standards of medical practice. However, for insured plans, applicable state law may require Aetna to apply an alternative criterion.

Important note:

We develop and maintain clinical policy bulletins that describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support our decisions regarding specific services. We use these bulletins and other resources to help guide individualized coverage decisions under our plans and to determine whether an intervention is **medically necessary**, **experimental, investigational, or unproven**. They are subject to change. You can find these bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]. You can also contact us. See the *Contact us* section for how.

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) determining the services subject to a treatment plan requirement and (b) process of making medical necessity determinations that include a treatment plan requirement.

(a) Factors for determining the services subject to a treatment plan requirement

Factor	Applicable to M/S	Applicable to MH/SUD
The service is subject to medical necessity review	✓	✓
The service is ongoing and therapeutic in nature	✓	✓

- **The service is subject to medical necessity review** means the service is subject to a medical necessity review performed by licensed health care professionals to determine medical necessity and appropriateness of treatment for certain covered services. The **evidentiary standards and sources** upon which this factor is based are:
    - The outpatient M/S services and MH/SUD services to which a medical necessity review applies, as listed on Aetna's list of services that require a treatment plan.
    - The factors, evidentiary standards, and sources for determining services for which a medical necessity review, as implemented through the Aetna policies, procedures, and other materials discussed at length in Aetna's Medical Necessity NQTL Comparative Analysis.

- **The service is ongoing and therapeutic in nature**. Therapeutic services treat or manage an already diagnosed condition or disease. The **evidentiary standards and sources** upon which this factor is based are:
    - A service is considered therapeutic when it actively treats, improves, or manages a medical or behavioral health condition, rather than diagnosing or preventing a medical or behavioral health condition.
    - Clinical evidence from systematic reviews of well-designed and well-conducted investigations published in peer-reviewed journals and other materials discussed at length in Aetna's Medical Necessity NQTL Comparative Analysis.

(b) Factors for the process of making medical necessity determinations that include a treatment plan requirement

In the process of making medical necessity determinations, including the application of a treatment plan requirement, Aetna clinical staff apply clinical guidelines to a coverage request after verifying that the member is eligible for benefits, the services requested are not excluded from coverage, and benefits are available (i.e., limited benefits are not exhausted). The factors considered or relied upon in the process of making medical necessity determinations, including with respect to application of a treatment plan requirement are:

Factor	Applicable to M/S	Applicable to MH/SUD
Review of all available, pertinent, clinical information by appropriate clinical professionals	✓	✓
Individual needs of the member	✓	✓
Characteristics of the local health care delivery system	✓	✓

- **Review of all available, pertinent, clinical information by appropriate clinical professionals.** Appropriate clinical professionals review all pertinent clinical information submitted by members or providers as part of the coverage determination process. Clinical staff make coverage determinations using this member-specific clinical information to determine whether the coverage request meets the applicable criteria/guidelines. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA Standards and Guidelines, specifically, and UM 4 and MBHO UM 4: Appropriate Professionals, and UM 6 and MBHO UM 6: Clinical Information, as implemented through Aetna's National Clinical Services (NCS) Policy 503: Medical Review Policy and Procedure and NCS 503 Virginia amendment.

- **Individual needs of the member** means that Aetna clinical staff consider the individual needs of the member when applying clinical criteria or guidelines during the medical necessity determination process. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA Standards and Guidelines, specifically, UM2 and MBHO UM2: Clinical Criteria for UM Decisions, as implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure along with **National Clinical Services (NCS) 503 Medical Review – Virginia**

This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.

- **Characteristics of the local health care delivery system** means that Aetna clinical staff additionally considers the available services in the local health care delivery system and their ability to meet the member's specific health care needs during the medical necessity determination process. The health care delivery system encompasses all the people, institutions, and services that contribute to care coordination, patient flows, diagnosis, disease management, and health maintenance programs. The **evidentiary standards and sources** upon which this factor is based are:

- NCQA Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, as implemented through Aetna's policy NCS 503: Medical Review Policy and Procedure along with **National Clinical Services (NCS) 503 Medical Review – Virginia**
  - This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.

Step 3: Description of How Factors are Used in the Design or Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Quality care and service to members** is a factor and strategy supporting Aetna's medical necessity processes.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of quality care and service to members applies equally to all M/S and MH/SUD benefits and is one factor generally underlying Aetna's medical necessity programs, including medical necessity criteria that include a treatment plan requirement. Aetna plans meet NCQA Health Plan and Managed Behavioral Health accreditation requirements, which include utilization review policy and process standards for conducting medical necessity review. Aetna is committed to Health Plan and Managed Behavioral Health Organization accreditation as one means of demonstrating a commitment to continuous quality improvement and meeting customer expectations.

Aetna's National Quality Oversight Committee (NQOC) annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, with consideration of recommendations from the National Quality Advisory Committee (NQAC). The NQOC is an Aetna multidisciplinary committee composed of department personnel representing both M/S and MH/SUD expertise across several functional areas. The NQOC includes representation from Aetna's behavioral health business segment for all functions: medical directors, network management, clinical health services, customer service, and quality management. The NQAC is a multidisciplinary

committee, which meets quarterly, and is comprised of external practitioners, including both M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The purpose of the NQAC is to solicit feedback from Aetna's participating providers on various topics including M/S and MH/SUD medical necessity criteria. The NQOC considers the NQAC feedback and recommendations in adopting Aetna's M/S and MH/SUD medical necessity criteria. The NQOC voting member roster is included in Appendix H, and the NQAC voting member roster is included in Appendix I.

- Additionally, Aetna Policy NCS 503 Medical Review Policy and Review Procedure defines the criteria/guidelines used in medical reviews and describes the procedure for application of the clinical criteria in medical necessity reviews and decision-making.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards relied upon when designing this NQTL are the NCQA UM standards and NCQA MHBO UM standards, as implemented through Aetna's UM Program Description and Aetna policy NCS 503: Medical Review Policy and Procedure. These standards apply equally to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definitions as it applies to MH/SUD as compared to M/S benefits.

- **Accordance with generally accepted standards of medical practice** is a factor used in the design of this NQTL. Virginia's standard certificate of coverage defines generally accepted standards of medical practice for M/S as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and following the standards set forth in our clinical polices and applying clinical judgment." The certificate of coverage further details the relevant medical community for MH/SUD benefits as "health care providers practicing in relevant clinical specialties including child and adolescent psychiatry, adult psychiatry, psychology, clinical sociology, addiction medicine and counseling, and behavioral health treatment."

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor is comparably applied to all M/S and MH/SUD benefits, and is an underlying factor supporting Aetna's medical necessity programs. M/S and MH/SUD medical necessity reviews conducted by Aetna are in accordance with generally accepted standards of medical practice. Aetna's NQOC annually reviews and adopts Aetna's M/S and MH/SUD medical necessity criteria, with consideration of recommendations from NQAC, as described above.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL:*** The evidentiary standards considered and relied upon when designing this NQTL are peer-reviewed published medical literature, including literature indexed in the National Library of Medicine PubMed Database.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: In the design of this NQTL, this factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor or its applicability, as it applies in the same way to MH/SUD and M/S benefits. While the governing definitions of generally accepted standards of care are not identical between M/S and MH/SUD benefits, both are based on credible scientific evidence recognized by the relevant medical communities, and this definition is applied comparably in the application of this NQTL.

- **Cost management** is one factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of cost management applies equally to all M/S and MH/SUD benefits. Cost management is a general factor supporting the design of Aetna's medical necessity programs, including medical necessity criteria that include a treatment plan requirement.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: With respect to the design of medical necessity, cost management does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from the factor of cost management, its applicability, or its definition, as it applies in the same way as a general design factor to MH/SUD and M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of quality care and service to members, accordance with generally accepted standards of medical practice, and cost management apply equally and agnostically to both M/S and MH/SUD benefits in the general design of medical necessity, and by extension, treatment plan requirements. While the governing

definitions of medical necessity differ between M/S and MH/SUD benefits, both are based on generally accepted standards of care and are applied to evaluate the clinical appropriateness of requested services. They are interrelated because they collectively ensure that the plan covers only medically necessary, effective, safe, and cost-efficient care for beneficiaries and plan participants. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective medical necessity review process, including when a treatment plan is required. Similarly, no one factor is weighted more than another.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in the application of a treatment plan requirement for: (a) determining the services subject to a treatment plan requirement and (b) the process of making medical necessity determinations that include a treatment plan requirement.

(a) Factors for determining the services subject to a treatment plan requirement

- **The service is subject to precertification** means the service is subject to pre-service utilization review performed by licensed health care professionals to determine medical necessity and appropriateness of treatment for certain covered services.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. As described below, a treatment plan is required for services that are on the precertification list and are ongoing and therapeutic in nature.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Precertification is required for certain outpatient services as listed on Aetna's National Precertification List and Member Precertification List. The factors, evidentiary standards, and sources for determining services for which precertification is required, as implemented through Aetna policies, procedures, and other materials, are discussed in detail in Aetna's Precertification NQTL Comparative Analysis.
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
    (d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **The service is ongoing and therapeutic in nature.** Therapeutic services treat or manage an already diagnosed condition or disease.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Therapeutic services treat or manage an already diagnosed condition or disease. Ongoing M/S and MH/SUD services that are therapeutic in nature are subject to a treatment plan requirement as a part of the medical necessity review process in order to determine whether continued services are medically necessary, according to the appropriate clinical guidelines. For selection of clinical guidelines to be used by Aetna clinicians when making medical necessity determinations, Aetna considers generally accepted standards of medical practice, annually reviews the medical necessity criteria and procedures for applying them and updates the criteria when appropriate.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: A service is considered therapeutic when it actively treats, improves, or manages a medical or behavioral health condition, rather than diagnosing or preventing a medical or behavioral health condition. Therapeutic services show clear, objective or subjective improvement, with clinical evidence that the service improves patient outcomes. This evaluation is based on evidence in the peer-reviewed published medical literature, technology assessments and structured evidence reviews, evidence-based consensus statements, expert opinions of healthcare providers, and evidence-based guidelines from nationally recognized professional healthcare organizations and government public health agencies. In developing M/S and MH/SUD CPBs, for each medical technology evaluated, the Clinical Policy Research and Development Team conducts a comprehensive search of the peer-reviewed published medical literature, assesses the regulatory status of the technology, reviews relevant evidence-based clinical practice guidelines and related documents, and reviews relevant technology assessments indexed in the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database. In addition, the opinions of relevant experts may be obtained when necessary. For Aetna's ABA Medical Necessity Guide, a multidisciplinary committee of health care professionals within and external to Aetna Behavioral Health developed and approved the guidelines based on extensive review of the literature on the use of ABA to treat autism spectrum disorder and a comparative review of the guidelines of other health insurers. The NQOC, as described above, and including representation of both M/S and MH/SUD clinicians and professionals, annually reviews and adopts the M/S and MH/SUD medical necessity criteria including CPBs and the ABA Medical Necessity Guide, with consideration of recommendations from the NQAC non-staff network practitioners, as described above.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

Relationship, ordering, and weighting of multiple factors: The factors listed above apply equally to M/S and MH/SUD benefits. For Aetna to require a treatment plan as a component of a medical necessity review, the service must meet both factors: 1) subject to precertification and 2) be ongoing and therapeutic in nature. The factors are interrelated and weighted equally to ensure that Aetna employs an appropriate and effective medical necessity determination process.

(b) Factors for the process of making medical necessity decisions that include a treatment plan requirement

In the process of making M/S and MH/SUD medical necessity determinations, including with respect to treatment plan requirements, Aetna clinical staff apply clinical guidelines/criteria to a coverage request after verifying that the member is eligible for benefits, the services requested are not excluded from coverage, and benefits are available (i.e., limited benefits are not exhausted). For the three (3) applicable services identified herein, the treatment plan requirement is one element of the applicable clinical guidelines for the service. The relevant clinical guidelines are contained within the medical necessity guidelines for the M/S and MH/SUD services identified in Step 1. The following explains how the factors are used in the process of making medical necessity determinations:

- **Review of all available, pertinent, clinical information submitted as part of the coverage determination process by appropriate clinical professionals.** Clinical staff make coverage determinations using member-specific clinical information, including the member's treatment plan, to determine whether the coverage request meets the applicable criteria/guidelines.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. The purpose of the written treatment plan is to assist in determining medical necessity, and the treatment plan is one element considered during the medical necessity review. Clinical staff draw upon their training and expertise to make coverage determinations using all available, pertinent, member-specific clinical information, including the treatment plan with specifically defined target behaviors, records of symptom frequency, rate, intensity, duration, or other objective measures of baseline levels, and established quantifiable criteria for progress, to determine whether the coverage request meets the applicable criteria/guidelines.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon in the application of this factor are NCQA UM Standards and Guidelines, specifically, UM 4 and MBHO 4: Appropriate

Professionals and UM 6 and MBHO UM 6: Clinical Information, as implemented through Aetna's Policy NCS 503: Medical Review Policy and Procedure and NCS 505: Denial of Coverage Policy. These guidelines provide steps in the medical necessity review, require the use of all information relevant to a member's care when making UM decisions, and require that denial determinations be made only by an appropriate clinical professional. NCQA UM 4 and MBHO UM 4, Appropriate Professionals, include requirements relating to the assessment of clinical information used to support UM decisions by qualified, licensed, health professionals. Additionally, professionals who review denials of care based on medical necessity must have education and experience in medical or clinical practice. NCQA UM 6 and MBHO UM 6, Clinical Information, require the use of all information relevant to a member's care when making UM decisions. If enough clinical information relevant to the medical necessity criteria is not provided with the request, Aetna will attempt to obtain the clinical information, including the treatment plan, needed to make a decision. Additionally, the associated medical necessity criteria specify what the written treatment plan for a specific service should include.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. This necessarily involves individualized evaluations and determinations for each member, using the treatment plan along with other medical records. A licensed clinician evaluates clinical coverage requests using the applicable guidelines. Clinical staff draw upon their training and expertise in applying clinical review criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. If the clinician cannot approve the request, it must be forwarded to a M/S or MH/SUD Medical Director or consultant psychiatrist, psychologist, or BCBA-D for review. While licensed clinical staff can issue M/S and MH/SUD coverage approvals, a Medical Director or psychiatrist/psychologist/BCBA-D is responsible for any M/S and MH/SUD denial of coverage, including stating and documenting the rationale for any denial. Additional information relating to the process of making M/S and MH/SUD medical necessity determinations is included in Step 4, Part 2 below.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S benefits.

- **Individual needs of the member** are considered when clinical staff make coverage determinations using member-specific clinical information, including the written treatment plan, to determine whether the coverage request meets the applicable criteria/guidelines.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Aetna's clinical staff consider the individual needs of the member, including documentation in a treatment plan of specific target behaviors, records of symptom frequency, rate, intensity, duration, or other objective measures of baseline levels, and quantifiable criteria for progress, when applying the above criteria/guidelines in the medical necessity determination process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon in the application of this factor are NCQA Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decisions, which are implemented through Aetna's Policy NCS 503: Medical Review Policy and Procedure. These NCQA guidelines specify that at least the following characteristics are considered when applying M/S and MH/SUD clinical guidelines to each individual: 1) age; 2) comorbidities; 3) complications; 4) progress of treatment; 5) psychosocial situation; and 6) home environment, when applicable. Additionally, as required by NCS 503, Aetna clinical staff consider the individual's need for skilled care and risk related to ethnicity or genetic factors.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff, as described above in the preceding factor, draw upon their training and expertise when reviewing the individual needs of the member and applying clinical criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. This necessarily involves individualized evaluations and determinations for each member, using the treatment plan along with other medical records. Additional information relating to the process of making M/S and MH/SUD medical necessity determinations is included in Step 4, Part 2 below.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

- **Characteristics of the local health care delivery system** means clinical staff considers the available services in the local health care delivery system and their ability to meet the member's specific health care needs in applying clinical criteria. The health care delivery system encompasses all the people, institutions, and services that contribute to care coordination, patient flows, diagnosis, disease management, and health maintenance programs.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits. Aetna's clinical staff considers characteristics of the local health care delivery system when applying the above criteria or guidelines in the medical necessity determination process.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon in the application of this factor are

NCQA UM Standards and Guidelines, specifically, UM 2 and MBHO UM 2: Clinical Criteria for UM Decision, as implemented through Aetna Policy NCS 503: Medical Review Policy and Procedure. These NCQA guidelines provide for consideration of available services in the local delivery system and their ability to meet the member's specific health care needs, in the application of medical necessity guidelines. Aetna's policy NCS 503 details the components clinical staff consider, which apply to both M/S and MH/SUD reviews:

- Available services and their ability to meet the member's specific health care needs;
- The ability of the provider to meet the member's cultural and language needs, as appropriate;
- The availability of highly specialized services, such as detoxification facilities;
- The availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and,
- The ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Aetna's clinical staff, as described in the preceding factor, draw upon their training and expertise when reviewing the characteristics of the local health care delivery system and applying clinical criteria/guidelines to make medical necessity determinations for M/S and MH/SUD services. This necessarily involves individualized evaluations and determinations for each member, using the treatment plan along with other medical records. Additional information relating to the process of making M/S and MH/SUD medical necessity determinations is included in Step 4, Part 2 below.

(d) ***Deviations or variations from a factor***: There is no deviation or variation from this factor, its applicability, or its definition, as it applies in the same way to MH/SUD and M/S services.

Relationship, ordering, and weighting of multiple factors: The factors listed above apply equally to M/S and MH/SUD benefits subject to a treatment plan requirement. While applying Aetna's medical necessity criteria/guidelines, Aetna's clinical staff apply their training, expertise, and clinical judgment to review all available, pertinent, member-specific information contained in the written treatment plan as well as other medical records, which is used to consider the individual needs of the member and the characteristics of the local health care delivery system. No factor is

weighted more heavily than the other. The factors are interrelated, and all operate together to ensure that Aetna employs an appropriate and effective medical necessity determination process.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Aetna requires a treatment plan as part of the medical necessity review for select outpatient services. Accordingly, a treatment plan requirement applies to the following benefit classifications: 1) in-network outpatient-all other and 2) out-of-network outpatient-all other. As noted in Step 2, Part 1, the factors used in the design of medical necessity, and by extension, treatment plan requirements are: 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, all of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. These general design factors are the basis and rationale underlying Aetna's policies and processes related to medical necessity, which include treatment plan requirements. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, these factors apply equally to both benefit types.

Quality care and service to members, as defined in Step 2, Part 1, above, is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD

benefits. As provided in **Aetna's UM Program Description,** applicable to both M/S and MH/SUD benefits, Aetna seeks to provide members with access to quality care and service while coordinating needed benefits. The UM Program Description supports Aetna's medical necessity review processes and details the accountability and structure of the committees responsible for reviewing, updating, and adopting the clinical criteria used in medical necessity reviews, including medical necessity reviews where a treatment plan is required, and the policies and procedures for applying clinical criteria. As explained above, each year, Aetna's NQAC reviews, and Aetna's NQOC adopts, Aetna's M/S and MH/SUD medical necessity criteria/guidelines, including Aetna CPBs and the ABA Medical Necessity Guide that include a treatment plan requirement. As written in the UM Program Description, the NQAC role includes "review of clinical criteria such as UM criteria, BH clinical criteria, Medical and BH Clinical Policy Bulletins (CPBs) and protocols for adoption by the NQOC." The role of the NQOC includes "adopting clinical criteria for both medical and behavioral health care and protocols with consideration of recommendations from the National Quality Advisory Committee (NQAC)." As set forth above, the NQAC is a multidisciplinary committee, which meets quarterly, and is comprised of external practitioners, including M/S and MH/SUD providers who participate in Aetna's network, and internal members who collaborate on quality initiatives. The purpose of the NQAC is to solicit feedback from Aetna's participating providers on various topics including M/S and MH/SUD medical necessity criteria. The NQOC, an Aetna body including representation of M/S and MH/SUD clinicians, considers the NQAC feedback and recommendations in adopting the M/S and MH/SUD medical necessity criteria. The factor of quality care and service to members, based upon evidentiary standards of NCQA UM Standards and NCQA MBHO UM Standards is further articulated through various Aetna National Clinical Services policies which apply equally to M/S and MH/SUD benefits and are discussed in Step 4, Part 2 below.

Accordance with generally accepted standards of medical practice, as defined in Step 2, Part 1, is a general design factor that does not distinguish between, and is comparably applied to, both M/S and MH/SUD benefits. Virginia's certificate of coverage defines generally accepted standards of practice as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and following the standards set forth in our clinical policies and applying clinical judgment," and the MH/SUD definition further identifies the relevant medical community. All M/S and MH/SUD medical necessity determinations are to be made in accordance with generally accepted standards of medical practice, pursuant to NCS 503: Medical Review Policy and Procedure. This factor is further articulated through the requirements for, and selection of, medical necessity guidelines used by Aetna clinicians conducting medical necessity reviews for M/S and MH/SUD services, implemented through NCS 503 and further discussed in Step 4, Part 2, below. In general, guidelines/criteria used (the applicable M/S CPBs and ABA Medical Necessity Guide) are in accordance with generally accepted standards of medical practice.

Aetna's **UM Program Description** refers to each of the design factors, including cost management. The UM Program Description provides that the focus of Aetna's utilization management program, as generally applicable to both M/S and MH/SUD benefits, is to provide access to care and services as well as quality, cost-effective, care in a timely manner. The goals and objectives of the UM program include efforts to "improve the clinical and cost-effectiveness of practitioner and provider practice patterns by promoting the use of evidence based clinical guidelines and care paths." Cost management as a design factor is further articulated in CVS Health public filings, which acknowledge that failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (see, e.g., Form 10-K at page 34: "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). While these materials refer to the general design factors of promotion of cost management and clinically appropriate utilization, there is no written documentation that more specifically explains how the factors of cost management and clinically appropriate utilization were used in the design of medical necessity with respect to M/S and MH/SUD benefits.

These design factors, 1) quality care and service to members; 2) accordance with generally accepted standards of medical practice; and 3) cost management, apply equally to both M/S and MH/SUD benefits and are not applied incomparably, or more stringently, to MH/SUD benefits in the benefit classifications noted above. Similarly, there are no deviations or variations from these three factors, as they apply to the design of medical necessity, and, by extension, treatment plan requirements. As written, the processes, strategies, evidentiary standards or other factors used in designing treatment plan requirements with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing treatment plan requirements with respect to M/S benefits across the applicable benefit classifications.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, treatment plan requirements apply to the following benefit classifications: 1) in-network outpatient-all other and 2) out-of-network outpatient-all other. As set forth above, Aetna applies a treatment plan requirement to 3 total M/S and MH/SUD services. Of those, 1 service is an MH/SUD service and 2 are M/S services. As noted in Step 2, Part 2, different factors are applied for: (a) determining the services subject to a treatment plan requirement and (b) the process of making medical necessity determinations that include a treatment plan requirement. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying a treatment plan requirement to MH/SUD

benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying treatment plan requirements to M/S benefits in the applicable benefit classifications.

(a) Determining the services subject to a treatment plan requirement

As noted in Step 2, Part 2, the factors used in application of treatment plan requirements for determining the list of services subject to a treatment plan requirement are 1) the service is subject to precertification and 2) the service is ongoing and therapeutic in nature. Services subject to a treatment plan requirement are a subset of those subject to precertification, as the member's treatment plan is reviewed during the application of the medical necessity criteria through the medical necessity review process. The processes, strategies, evidentiary standards, and other factors used in determining the services that are subject to precertification are analyzed in detail in Aetna's Precertification Nonquantitative Treatment Limitation Comparative Analysis, including the written materials used to apply precertification to M/S and MH/SUD benefits. Of the services subject to precertification, a written treatment plan is required during the course of the medical necessity review for services that are ongoing and therapeutic in nature. The treatment plan requirement is documented in the medical necessity guidelines, which are available to members and providers. External links to the medical necessity guidelines pertaining to M/S and MH/SUD services subject to a treatment plan requirement are included in Step 1. As written, Aetna's ABA Medical Necessity Guide and the CPBs for skilled private duty nursing and hyperbaric oxygen therapy include the requirement for treatment plans as part of the medical necessity review. Aetna's skilled private duty nursing CPB sets forth: "Aetna considers private duty nursing (PDN) services medically necessary when *all* of the following requirements are met: 1. The services are ordered by a licensed physician (MD or DO) as part of a treatment plan for a covered medical condition; *and* 2. The attending physician must approve a written treatment plan with short and long term goals specified…" Similarly, Aetna's hyperbaric oxygen therapy (HBOT) CPB includes documentation requirements: "Wounds must be evaluated, with photographic documentation with ruler, after every 15 treatments and/or at least every 30 days during administration of HBOT." Finally, Aetna's ABA Medical Necessity Guide includes a requirement that: "The treatment plan documents have specific identified target behaviors related to the condition that are clearly defined…" The ABA Medical Necessity Guide continues to provide details about what constitutes a treatment plan. All of these medical necessity guidelines include references to evidence-based, peer-reviewed medical literature, and these medical necessity guidelines are reviewed and adopted each year by Aetna's NQOC. Aetna's analysis of the "as written" material used in the application of treatment plan requirements, to determine the services which require a treatment plan, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD benefits and not more stringently applied to MH/SUD benefits.

(b) The process of making medical necessity determinations that include a treatment plan requirement

As set forth above in Step 2, Part 2, the factors used in application, for the process of performing medical necessity determinations that require a treatment plan are 1) review of all available, pertinent, clinical information, including a written treatment plan, submitted as part of the coverage determination process by appropriate clinical professionals; 2) individual needs of the member, including the written treatment plan; and 3) characteristics of the local health care delivery system. These processes are described in detail in the Aetna National Clinical Services (NCS) policies and procedures pertaining to medical necessity review. Aetna maintains one set of written policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to make medical necessity determinations that include a treatment plan requirement for both M/S and MH/SUD services:

- NCS 503: Medical Review Policy & Procedure
- NCS 503: Medical Review Policy & Procedure Virginia Amendment -
- **-** This Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 503 Medical Review Policy and Procedure. This amendment will be used in conjunction with NCS 503 to comply with Virginia requirements.
- NCS 505: Denial of Coverage Policy and Notification
- NCS 505: Denial of Coverage Policy and Notification Virginia Amendment - This Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 505 Denial of Coverage Policy and Notification. This amendment will be used in conjunction with NCS 505 to comply with Virginia requirements
- NCS 506: Peer-to-Peer Review Policy
- NCS 506: Peer-to-Peer Review Policy Virginia Amendment - This Amendment is written to meet regulatory and statutory requirements under Virginia law that impact NCS 506 Peer-to-Peer Review Policy. This amendment will be used in conjunction with NCS 506 to comply with Virginia requirements.

Each of these policies is discussed in turn below, demonstrating that they support the factors outlined above and are comparably applied, as written, to M/S and MH/SUD services.

NCS 503: Medical Review Policy & Procedure establishes the process of medical review and documents the written clinical criteria/guidelines adopted by the NQOC, to be used by Aetna's clinicians in making medical necessity determinations. This policy applies equally to M/S and MH/SUD services. For both M/S and MH/SUD services, the clinical reviewers exercise their clinical judgment, guided by the written clinical criteria/guidelines, to make medical necessity determinations, including with respect to application of treatment plan requirements. NCS 503 sets forth Aetna's medical necessity criteria, which includes, relevant to treatment plan requirements, Aetna's CPBs for skilled private duty nursing and hyperbaric oxygen therapy, and Aetna's ABA Medical Necessity Guide.

- **Aetna Clinical Policy Bulletins (CPBs)** (skilled private duty nursing and hyperbaric oxygen therapy) – Aetna CPBs describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's medical necessity decisions regarding specific M/S and MH/SUD services.

- **ABA Medical Necessity Guide** – Aetna's ABA medical necessity guidelines come from extensive review of the literature on the use of applied behavior analysis to treat autism spectrum disorder and a comparative review of the guidelines of other health insurers. A multidisciplinary committee of health care professionals within and external to Aetna Behavioral Health developed and approved the guidelines based on these reviews.

These guidelines do not replace professional judgment exercised by properly trained, licensed, and experienced clinicians and professionals who evaluate the provision of services in accordance with accepted standards of care. As explained in NCS 503, individual M/S and MH/SUD medical necessity determinations are afforded independent clinical consideration based on the member's presentation. As listed in NCS 503, staff considers the individual needs of the member when utilizing guidelines, including, but not limited to age, co-morbidities, complications, progress of treatment, need for skilled care, psychosocial situation, risk related to ethnicity or genetic factors and home environment, when applicable. Staff additionally considers the following characteristics of the local health care delivery system during the coverage determination process: the ability of the provider to meet the member's cultural and language needs, as appropriate; the availability of highly specialized services, such as detoxification facilities; the availability and health plan coverage of skilled nursing facilities, sub-acute care facilities, transitional/outpatient facilities, partial hospitalization, and other step-down services, or home care in the service area to support the member after discharge from the hospital; and, the ability of the provider (e.g., physician or admitting hospital or other hospitals in the service area) to provide all recommended acute care services within the estimated length of stay and within a time sensitive manner relative to the severity of the member's clinical condition. NCS 503 further notes that approval decisions may be automated when appropriate. Automation uses clinical information submitted by the provider and compares it to our clinical policies to render an approval decision, based on individualized clinical considerations, using the tools outlined in NCS 503. For both M/S and MH/SUD medical necessity reviews, all adverse decisions are made by medical directors, never by automation or clinical staff who are not medical directors, as required by NCS 505: National Clinical Services Denial of Coverage Policy, discussed below. Aetna follows applicable state laws in the administration of medical necessity review and treatment plan review. More stringent state law requirements, including whether and how often a treatment plan may be required, supersede Aetna's standard processes, as documented pursuant to NCS 503 and Aetna's Controlling State guidelines. Thus, the "as written" material contained in NCS 503 pertaining to the medical review process is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

Additionally, **NCS 505** defines and outlines the handling of denial of coverage determinations, including the responsibility for issuing clinical and administrative denial decisions, documentation requirements for denial decisions, and notification requirements for these coverage decisions. As written, this policy applies equally to M/S and MH/SUD services and specifies that only M/S and MH/SUD medical directors can deny clinical coverage decisions. Because the processes are the same, the "as written" material contained in NCS 505 pertaining to the handling of coverage determination denials is applied comparably to M/S and MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

NCS 506 outlines the peer-to-peer review process through which a treating practitioner, a clinician on behalf of the treating practitioner (e.g., genetic counselor for BRCA precertification requests) or a physician on behalf of a facility (for precertification denials) may request a discussion with a peer reviewer (licensed health plan physician medical director) or behavioral health consultant psychiatrist/psychologist/board certified behavior analyst-doctoral (BCBA-D), to discuss a clinical denial of coverage determination. Peer-to-peer is not an additional level of review or an appeal. It is a focused discussion between the provider representative and the peer reviewer. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D considers all available information when conducting a peer-to-peer review. The peer reviewer or behavioral health consultant psychiatrist/psychologist/BCBA-D reviews the applicable clinical criteria/guidelines in NCS 503, the clinical information that is present before and during the peer-to-peer discussion and uses clinical judgment to make a decision. For M/S, peer-to-peer reviews are conducted after a denial determination, upon request. For MH/SUD services, when clinically appropriate, peer-to-peer reviews are offered and conducted prior to the issuance of the initial coverage determination, in addition to peer-to-peer reviews that are available after a denial determination. As written, the process for peer-to-peer review is largely the same for M/S and MH/SUD, except that for MH/SUD services, Aetna may offer a peer-to-peer review before a determination has been issued, in addition to the peer-to-peer review that is available post-determination. Based upon the foregoing, the written material contained in NCS 506 pertaining to peer-to-peer review is comparably applied to MH/SUD services and is not more stringently applied to MH/SUD services than to M/S services.

In sum, Aetna's analysis demonstrates that as written, the processes, strategies, evidentiary standards, and other factors used in applying treatment plan requirements to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying treatment plan requirements to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

As noted in Step 1, Part 2, treatment plan requirements apply to the following benefit classifications: 1) in-network outpatient–all other and 2) out-of-network outpatient–all other. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying medical necessity to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying medical necessity to M/S benefits.

In operation, Aetna requires a treatment plan as part of the medical necessity review for M/S and MH/SUD in-network and out-of-network outpatient–all other services in the limited circumstances discussed herein. For outpatient M/S and MH/SUD services, Aetna conducts a review of the treatment plan, in operation, for services: 1) subject to precertification and 2) where the services are ongoing and therapeutic in nature. As set forth above, Aetna M/S and MH/SUD CPBs and ABA Medical Necessity Guide describe the generally accepted standards of medical practice, credible scientific evidence, and prevailing clinical guidelines that support Aetna's treatment plan requirements regarding specific M/S and MH/SUD services. These medical necessity criteria, in conjunction with the terms of the member's benefit plan, are used to help guide individualized coverage determinations under Aetna's medical plans and to determine whether a treatment plan requirement applies.

In operation, Aetna requires a treatment plan as defined herein, for two M/S services, and one MH/SUD service. There are no services that do not require a treatment plan initially but require a treatment plan for continued services.

The specific M/S and MH/SUD services for which a treatment plan is required, in operation, are:

Service	Link	Benefit Type
Applied behavior analysis	aetna.com/cpb/medical/data/500_599/0554.html	MH/SUD
Hyperbaric oxygen therapy	aetna.com/cpb/medical/data/100_199/0172.html	M/S

Skilled private duty nursing	aetna.com/cpb/medical/data/100_199/0136.html	M/S

In sum, based upon review of the data and information addressed herein, the factors, evidentiary standards and sources for establishing treatment plan requirements and conducting the medical necessity review process including with respect to treatment plan requirements, are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits in operation. Based on the data and reviews discussed above, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying treatment plan requirements to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying treatment plan requirements with respect to M/S benefits.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, a treatment plan is an individualized plan of care where: objective measures of baseline levels are recorded; specific goals are clearly defined; and quantifiable criteria for progress are established. A written treatment plan is required as a part of the medical necessity determination for certain M/S and MH/SUD services in the following benefit classifications: 1) in-network outpatient–all other and 2) out-of-network outpatient–all other. Step 2 identified the factors that are used 1) to determine the services subject to a treatment plan requirement and 2) in the process of making medical necessity determinations that include a treatment plan requirement. Step 3 explained the evidentiary standards and sources for those factors, and how they are used in the design and application of treatment plan requirements. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD services. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD services and concluded that there are no written differences in that application that results in any MH/SUD services being treated more stringently than, or incomparably to, M/S services. Finally, Step 5 demonstrated that, in operation, Aetna applies the factors and evidentiary standards comparably to M/S and MH/SUD services in requiring a treatment plan.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors, evidentiary standards, and sources to M/S and MH/SUD benefits in determining which services require a treatment plan as part of the medical

necessity determination, and in conducting medical necessity reviews that include a treatment plan requirement. Three factors are used in the context of designing medical necessity, and by extension, treatment plan requirements: 1) quality care and service to members; 2) clinically appropriate utilization; and 3) cost management, all of which are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services. Aetna maintains one UM Program Description, which is equally applicable to M/S and MH/SUD benefits, that sets forth the focus and goals of Aetna's utilization management program. The focus and goals align to the three general design factors, which provide a basis and rationale underlying Aetna's policies related to medical necessity, and by extension, treatment plan requirements for M/S and MH/SUD services. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits.

In the application of treatment plan requirements, the factors used to determine services subject to a treatment plan requirement are 1) the service is subject to precertification and 2) the service is ongoing and therapeutic in nature. As demonstrated in Step 3, the evidentiary standards, sources, and other factors used in the application of these factors, specifically, the clinical evidence in peer-reviewed published medical literature, technology assessments and structured evidence reviews, evidence-based consensus statements, expert opinions of healthcare providers, and evidence-based guidelines from nationally recognized professional healthcare organizations and government public health agencies, are equally applicable to M/S and MH/SUD benefits. The medical necessity guidelines (i.e., hyperbaric oxygen therapy and skilled private duty nursing CPBs and Aetna ABA Medical Necessity Guide) contain the evidentiary standards that are used in the application of treatment plan requirements. As demonstrated in Step 4, these medical necessity guidelines provide the "as written" material used in the application of treatment plan requirements, to determine which services require a treatment plan as part of the medical necessity determination.

Additionally, the factors used in the process of making medical necessity determinations that include a treatment plan requirement are 1) review of all available, pertinent, clinical information by appropriate clinical professionals; 2) individual needs of the member; and 3) characteristics of the local health care delivery system. These factors support Aetna's written processes for performing medical necessity reviews, including with respect to treatment plan requirements. These processes are described in detail in the Aetna Utilization Management policies and procedures pertaining to medical necessity. Aetna maintains one set of written UM medical review policies that are equally applicable to M/S and MH/SUD and represent the strategies and processes that Aetna employs to perform medical necessity reviews, including treatment plan requirements, for M/S and MH/SUD services. The factors, and the written policies based on the same, apply equally and are agnostic to whether the benefit is M/S or MH/SUD. As further demonstrated in Step 5, an in-operation review of the services subject to a treatment plan requirement shows that only one MH/SUD service (applied behavior analysis) is subject to a treatment plan requirement, compared to two M/S services (hyperbaric oxygen therapy and skilled private duty nursing). From this information, Aetna may conclude that the factors, evidentiary

standards, and sources used to design and apply treatment plan requirements to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying treatment plan requirements with respect to M/S benefits across the applicable benefit classifications. The treatment plan NQTL is designed and applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Behavioral Health Medical Director, Quality and Mental Health Parity, Medical Doctor board certified in Psychiatry • Senior Clinical Solutions Lead, Behavioral Health, PsyD • Senior Manager, Clinical Behavioral Health, PhD • Sr. Principal Clinical Lead, Clinical Services Utilization Management

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Nonquantitative Treatment Limitation Comparative Analysis:

PARTICIPATING PROVIDER REIMBURSEMENT

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of participating provider reimbursement and* ***(2)*** *an identification of all medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits to which participating provider reimbursement applies and a description of the benefits classifications to which the M/S and MH/SUD benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Participating Provider Reimbursement [45 CFR 146.137(c)(1)(i)]

Participating provider reimbursement is payment to in-network providers for covered services provided to members. This is the amount that a network provider has agreed to accept or that Aetna has agreed to pay. This NQTL is implemented by the plan's definition of negotiated charge. Out of network reimbursement is documented as a separate NQTL.

For professional providers, the preferred fee schedule for both M/S and MH/SUD participating practitioners is the Aetna Market Fee Schedule ("AMFS"). AMFS establishes rates for service codes at the market level, based on ZIP codes, geographic specifications, and whether the service is office-based or facility-based. Aetna's Medical Economics Unit (MEU) and Network teams collaborate to establish rates and update them periodically. When a professional provider is unwilling to accept the AMFS rates, the AMFS is used as a starting point for contract negotiations. For both M/S and MH/SUD participating facilities, there is no preferred fee schedule for facilities, and each fee schedule is negotiated individually.

MHPAEA requires plans to compare benefits within a classification. Insurers are permitted to sub-classify outpatient visits into office visits and "all other.", which Aetna has chosen to do. "All other" refers to outpatient services provided by a healthcare professional in a manner that the predominant trait of the outpatient service is something other than direct, personal interaction with the professional. These services are primarily dependent on a technological test or device, as well as surgeries. Benefit classification assignment is not dependent on provider/facility types but rather the services performed.

Aetna has chosen to classify each benefit into one of the following categories:

- inpatient in-network
- inpatient out-of-network
- outpatient office visit in-network
- outpatient office visit out-of-network
- outpatient all other in-network
- outpatient all other out-of-network
- emergency
- prescription drugs

Aetna does not utilize any vendors when negotiating rates for participating providers.

The following materials describe participating provider reimbursement:

1. Plan Documents

With respect to participating (network) provider reimbursement, Virginia's standard ALIC certificate of coverage provides:

Certificate of Coverage – VA AL HCOC 14

> **Negotiated charge**
> This is the amount a **network [provider]** has agreed to accept or that we have agreed to pay them or a third-party vendor (including any administrative fee in the amount paid).

[For surprise bills, calculations will be made based on the median contracted rate.][Some **[providers]** are part of Aetna's network for some Aetna plans but are not considered **network [providers]** for your plan. For those **[providers]**, the negotiated **charge** is the amount that **[provider]** has agreed to accept for rendering services or providing **prescription** drugs to members of your plan.]

We may enter into arrangements with **network [providers]** or others related to:

- The coordination of care for members
- Improving clinical outcomes and efficiencies

Some of these arrangements are called:

- Value-based contracting
- Risk sharing
- Accountable care arrangements

These arrangements will not change the negotiated **charge** under this plan.]

2. Provider Contracts

Aetna's template provider contract for non-facility health care professionals sets forth the reimbursement agreement between Aetna and participating providers. The executed provider agreement includes a Product Addendum(a) and Service and Rate Schedule(s) specific to the provider's agreement with Aetna. Aetna uses the same template provider contract for M/S and MH/SUD practitioners.

Provider Agreement Template, Claims Submission and Payment

> Subject to Applicable Law, Provider agrees: (a) to accept the rates contained in the applicable Service and Rate Schedule(s), regardless of where services are provided, as payment in full for Covered Services (including for services that would be Covered Services but for the Member's exhaustion of benefits (e.g., above the annual maximum)).

Service and Rate Schedule Template, Definitions

> "**Aetna Market Fee Schedule**" (AMFS) **–** A fee schedule that is based upon the contracted location where services are performed. Company may periodically update this fee schedule.
>
> General
>
> a) Rates are inclusive of any applicable Member Copayment, Coinsurance, Deductible and any applicable tax including but not limited to sales tax. For procedures and/or services not specifically listed above, Provider agrees to accept then current AMFS as payment in full.
> b) Unless required by law, payment for services of Mid-level Practitioners (Nurse Practitioners, Certified Nurse Midwives, Physician Assistants and Registered Nurses) may be less than Physician services based on Company's then current payment policy.
> c) Payment for services of Clinical Psychologists, Psychiatric Nurses and any other Licensed Master Level Practitioner (Clinical Social Workers, Licensed Professional Counselors, Marriage/Family Therapists, Psychological Examiner, Drug and Alcohol Counselor, Pastoral Counselor) may be less than Company's then current payment methodology for Behavioral Health physician services.

3. Facility Contracts

Aetna's template provider contract for facility providers sets forth the reimbursement agreement between Aetna and participating providers. The executed provider agreement includes a Product Addendum(a) and Service and Rate Schedule(s) specific to the provider's agreement with Aetna. Aetna uses the same template provider contract for M/S and MH/SUD providers.

> Claims Submission and Payment. Subject to Applicable Law, Facility agrees:
> (a) to accept the rates contained in the applicable Service and Rate Schedule(s), regardless of where services are provided, as payment in full for Covered Services (including for services that would be Covered Services but for the Member's exhaustion of benefits (e.g., above the annual maximum));

4. Policies and Procedures

The following Aetna policies and procedures (P&Ps), which apply to both M/S and MH/SUD benefits, address participating provider reimbursement:

- **Network Policy 280: Aetna Market Fee Schedule Rate Development Policy and Procedure – Non-Facility Providers:** This policy and procedure outlines how Aetna's Medical Economics Unit (MEU) and the network teams establish Aetna Market Fee Schedule (AMFS) rates for participating M/S and MH/SUD providers.
- **Network Policy 281: Participating Provider Reimbursement Policy and Procedure:** This policy and procedure outlines the process by which Aetna designs participating provider reimbursement, and processes with respect to M/S and MH/SUD professional and facility reimbursement.
- **Network Policy 101: Contracting Guidelines Policy**. This policy outlines contracting guidelines when contracting with M/S and MH/SUD providers and identifies all related documentation and processes required prior to contract execution. This includes appropriate steps to accurately assess the operational and financial impact of proposed contracting methodologies prior to execution.
- **Payment Policy N004: Non-Physician Providers Payment Policy** addresses the reimbursement rate for specific non-physician M/S and MH/SUD providers.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii);] and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Benefits and Classification

Participating provider reimbursement applies to M/S and MH/SUD services in the following benefit classifications: **in-network inpatient; in-network outpatient,** both **office** and **all other** subclassifications, and **emergency.**

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **INN OV** ✔ **INN OP AO** ✔ **Emergency**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
Applies to all M/S benefits delivered in-network	Applies to all MH/SUD benefits delivered in-network

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146-137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of participating provider reimbursement. Each subpart includes:* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to participating provider reimbursement, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of participating provider reimbursement.

Factor	Applicable to M/S	Applicable to MH/SUD
Cost management	✓	✓
Market competitiveness	✓	✓

- **Cost Management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by measures including optimizing utilization of services, contracting with providers for agreed-upon rates, and implementing processes that are intended to reduce spending for services that are not covered and are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

- **Market competitiveness** is a **factor** and **strategy** used to design participating provider reimbursement. This factor aims to achieve total health care cost rates that are competitive with the total health care cost rates for similar products issued by others in the market, to achieve

premium pricing required to compete effectively and develop and maintain attractive networks with high-quality providers. The **sources and evidentiary standards** upon which this factor is based are:

- Stakeholder pressure to control costs of benefits.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) establishing and refreshing Aetna's preferred professional provider fee schedule, the AMFS; (b) establishing or evaluating a proposed facility fee schedule; and (c) negotiating participating facility and professional provider reimbursement rates.

(a) Factors for establishing and refreshing Aetna's preferred professional provider fee schedule (AMFS)

Factor	Applicable to M/S	Applicable to MH/SUD
Index rates	✓	✓
Service type	✓	✓
Market dynamics	✓	✓
Unit price trend target	✓	✓
Provider type	✓	✓

- **Index rates** are third-party rates used as a benchmark in developing the AMFS for M/S and MH/SUD services and contracting with providers for the negotiated charges. The **evidentiary standards and sources** for this factor are:
  - The Resource Based Relative Value Scale (RBRVS) payment methodology, a/k/a Medicare rates, developed by the Centers for Medicare and Medicaid Services (CMS). Where no Medicare rate is available, a hierarchy of other evidentiary standards are used as a benchmark to establish the rate.

- **Service type** bases reimbursement on the billing codes for M/S and MH/SUD services submitted by a provider. The **evidentiary standards and sources** for this factor are:
  - Reimbursement amounts are based on the billing codes submitted by a provider (e.g., initial assessments are generally reimbursed at a higher rate than follow-up

appointments). These billing codes are CPT (Current Procedural Terminology) and HCPCS (Healthcare Common Procedure Coding System) codes.

- **Market dynamics** refers to the unique characteristics of a market. The AMFS is set at the market level for each geographically defined Aetna market. The **evidentiary standards and sources** for this factor are:
    - Aetna Network Management's analysis of the market, including supply and demand, the carrier's market penetration compared to other carriers and networks, and any other relevant characteristics specific to that market.

- **Unit price trend target** refers to the percentage of unit price by which the network determines it can adjust overall M/S and MH/SUD rates when refreshing them. The **evidentiary standards and sources** for this factor are:
    - Claim utilization data.
    - Current network rates.
    - Estimated competitor unit price trends.
    - The provider contracts up for renewal that year.

- **Provider type** refers to the provider's licensure type (e.g., MD, DO, LCSW, RN). For both M/S and MH/SUD provider types, reimbursement rates are tiered based on practitioner licensure. The **evidentiary standards and sources** for this factor are:
    - Practitioner provider type, as implemented through Payment Policy N004: Non-Physician Providers Payment Policy.
    - The CMS Medicare Claims Processing Manual, which reduces payment for non-physician practitioners.

(b) Factors for establishing or evaluating a proposed facility fee schedule

Factor	Applicable to M/S	Applicable to MH/SUD
Scope and complexity of services	✓	✓
Index rates	✓	✓
Competitive data	✓	✓
Market dynamics	✓	✓

- **Scope and complexity of services** refers to the range of practice specialties, levels of care, and settings offered by the facility. The **evidentiary sources and standards** for this factor are:
    - Facility type (e.g., acute inpatient hospital, ambulatory surgical center, skilled nursing facility, residential treatment facility, psychiatric hospital).

- Service type, which bases reimbursement on the billing codes a facility submits, including CPT, HCPCS, and diagnosis codes. Service type also refers to inpatient or outpatient.

- **Index rates** are third-party rates used as a benchmark in developing or evaluating a facility fee schedule and contracting with providers for the negotiated charges. The **evidentiary standards and sources** for this factor are:
  - The Resource Based Relative Value Scale (RBRVS) and Diagnosis Related Groups (DRG) payment methodologies, a/k/a Medicare rates, developed by CMS.

- **Competitive data:** Refers to what competitors pay the facility for the same services, to the extent that can be determined from information publicly available. The **evidentiary sources and standards** for this factor are:
  - State and federal All Payer Claims Databases.
  - External consulting firm analyses of Aetna's discount position in the market compared to other carriers, using uniform data system discount submissions.
  - Rates Aetna pays other facilities.

- **Market dynamics** refers to the unique characteristics of a market. Local networks establish facility reimbursement strategies to take into consideration the unique characteristics of each market. The **evidentiary standards and sources** for this factor are:
  - Aetna Network Management's analysis of the market, including supply and demand, the carrier's market penetration compared to other carriers and networks, and any other relevant characteristics specific to that market.

(c) Factors for negotiating participating facility and professional provider reimbursement rates

Factor	Applicable to M/S	Applicable to MH/SUD
Unit price trend target	✓	✓
Provider leverage	✓	✓

- **Unit price trend target** refers to the percentage of unit price by which the network determines it can adjust overall M/S and MH/SUD rates when negotiating fee schedules. The **evidentiary standards and sources** for factor are:
  - Claim utilization data.
  - Current network rates.
  - Estimated competitor unit price trends.
  - The provider contracts up for renewal that year.

- **Provider leverage**, or bargaining power, refers to a professional provider's ability to negotiate a rate higher than AMFS or a facility's ability to negotiate higher rates. The **evidentiary standards and sources** for this factor are:
    - The relative scarcity of a professional provider's specialty or area of focus, or a facility provider's licensure and type of services provided, including whether network adequacy standards are met.
    - Member needs for that specialty/focus or facility type and services.
    - Whether the provider is part of a large health system or practice group that includes numerous specialties.
    - Plan sponsor demand and the number of members served by the provider.

Step 3: Description of How Factors are Used in the Design or Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Cost management** is a factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care for policyholders.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in-network. All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. In order to manage costs for both members and plans, Aetna attempts to negotiate favorable contracts, the goal of which is to reimburse providers fairly while managing plan costs. Efforts to appropriately manage cost, by establishing reimbursement rates based on the preferred professional provider fee schedule

(AMFS), appropriate evaluation of facility fee schedules, and negotiating favorable contracts, is a basis and rationale underlying Aetna's standards and procedures relating to participating provider reimbursement.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition, as it applies to MH/SUD as compared to M/S benefits.

- **Market competitiveness** is a factor used in the design of this NQTL as the basis for establishing standard rates and negotiating fee schedules, with the goal of achieving total health care cost rates that are competitive with the total health care cost rates for similar products issued by third parties in the market so as to achieve premium pricing required to compete effectively, attract and retain providers in the network, and drive membership growth.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in-network. All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. Promoting market competitiveness, by offering a health insurance product that is desirable to both members and providers, is a basis and rationale underlying Aetna's standards and procedures relating to participating provider reimbursement.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to be competitive in the market. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. This standard applies equally as a general concept to all M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition, as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of cost management and market competitiveness apply equally and agnostically to both M/S and MH/SUD benefits in the general design of participating provider reimbursement. These factors are interrelated because they collectively seek to ensure that Aetna appropriately reimburses participating providers. The ability to negotiate appropriate contracts with providers builds a strong provider network that is attractive to members, providers, and health plans. Promoting cost management and market competitiveness, together, keeps premiums affordable and manages risk to the health plan. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for appropriate participating provider reimbursement. Similarly, no one factor is weighted more than another in the design of this NQTL.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how the factors are used in the application of participating provider reimbursement, encompassing the components of: (a) establishing and refreshing Aetna's preferred professional provider fee schedule, the AMFS; (b) establishing or evaluating a proposed facility fee schedule; and (c) negotiating participating facility and professional provider reimbursement rates.

(a) Factors for establishing and refreshing Aetna's preferred professional provider fee schedule, the AMFS

- **Index rates** are third-party rates used as a benchmark in developing or refreshing the AMFS.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to M/S and MH/SUD benefits delivered in-network. All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. Index rates are used as a benchmark to establish and refresh the preliminary AMFS, which Network Management uses as a starting point for development of AMFS rates.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: In general, the evidentiary standard for this factor is the Medicare rate for the same service code. Where no Medicare rate is available, a hierarchy of other pricing sources is used as the index rate.

The first level of the index rate hierarchy is Medicare-based pricing sources. The RBRVS payment methodology, developed by CMS in consultation with the American Medical Association ("AMA"), assigns relative value units (RVUs) to service codes to reflect the physician or other provider work involved, practice expense, and liability insurance each service code entails. CMS applies a conversion factor to the RVU and an adjustment for the geographic area to calculate the resulting RBRVS rate. Other Medicare-based pricing sources are used for services and supplies

that do not fall under RBRVS. These are: DMEPOS (durable medical equipment, prosthetic, orthotic and supplies), PEN (parenteral and enteral nutrition), Clinical Lab Fee Schedule, and Medicare ASP (Average Sale Price). These Medicare-based rates are used as an index when developing rates for new service codes, as well as when refreshing M/S rates and rates for services that can be billed for both M/S and MH/SUD providers.

The second level of the index rate hierarchy is non-Medicare based pricing sources, which are used where Medicare-based services are not available. There are some services Medicare does not value through the RBRVS payment methodology, referred to as gap codes. Optum 360, a contracted vendor, values many of these gap codes in the Essential RBRVS GAP Methodology. When no RBRVS rate exists for a service code, Aetna uses the Optum rate as the index rate. For codes where there is no CMS or Optum rate, Aetna uses Developed Aetna Rate Table (DART) rates, which are based on Aetna's internal claims and national contract defaults. Additionally, national carveouts that apply to both M/S and MH/SUD services may be used when recommended by national workgroups and Medical Directors. For some specialized M/S benefits that are not valued by the index rate sources listed above, additional sources may be used when Medicare or Optum 360 vendor rates are not available. These sources are Average Wholesale Price (AWP) published by RJ Health, Manufacturers Acquisition Pricing (MAP) supplied by major immunization manufacturers, and the national DME fee schedule developed and maintained by the national network team. These sources do not apply to MH/SUD benefits because they do not value MH/SUD service codes.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Service type** refers to the billing codes a provider submits. These CPT and HCPCS codes represent the services provided to the member.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of service type applies to M/S and MH/SUD benefits delivered in-network. All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. The service type is used to determine the amount of reimbursement.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are CPT and HCPCS codes. The AMA issues, updates, and maintains these clinically valid code sets to accurately reflect current clinical practice and innovation in medicine. Aetna classifies codes as either "Medical Class" or "Behavioral Health

(BH) Class." Medical Class codes are most commonly billed by M/S providers, although they may also be billed by MH/SUD providers. BH Class codes are most commonly billed by MH/SUD providers, although they may also be billed by M/S providers. Aetna's Network Management classifies codes as medical or behavioral health. These decisions are based on empirical claim billing data, such that codes that may be billed by both M/S and MH/SUD providers are classified based on which provider type bills them most frequently. In establishing AMFS rates, for each service code, the MH/SUD provider rates are set at or above the rate for M/S providers.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Market dynamics** refers to the unique characteristics of a market, including supply and demand, the carrier's market penetration compared to other carriers and networks, and any other relevant characteristics specific to that market.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies to all M/S and MH/SUD benefits delivered in-network. All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. Market dynamics inform whether the proposed AMFS rates, based on the index rates for various service types, are adjusted for specific market needs. The assessment of market dynamics could also result in no adjustment to the proposed rates. Aetna's Network Head or Chief Network Operations Officer have final approval for the AMFS.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that is relied upon when applying this factor is Aetna's Network Management's analysis of the market, including supply and demand, Aetna's market penetration compared to other carriers and networks, and any other relevant characteristics specific to that market. Supply and demand refers to how many providers there are in a particular geographic area who provide the same services and how much need there is for those services among the membership, including whether the network adequacy standards are met (see Aetna's Network Adequacy NQTL Comparative Analysis). Market penetration refers to evaluation of how many plan members are in the market, which results in greater patient volume for network providers.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Unit price trend target** refers to the percentage of the unit price by which the network determines it can adjust overall M/S and MH/SUD rates when refreshing the AMFS.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of unit price trend target applies to all M/S and MH/SUD benefits delivered in-network. All benefits delivered in-network are subject to participating provider reimbursement. Aetna's MEU establishes the unit price trend target, and each network team has a goal of meeting the target, inclusive of refreshing AMFS rates and individual contract negotiation.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are claim utilization data, current network rates, estimated competitor unit price trends, and the provider contracts up for renewal that year.

Using prior year claim utilization as a baseline, Aetna's MEU forecasts costs for future claim payments and determines how much the costs can increase while remaining competitive in the market from both a provider reimbursement and member premium perspective. Prior year claim utilization forms the baseline for what claim utilization to expect in the future. Current network rates are used to predict costs for forecasted claim utilization, forming the starting point from which rates may increase. Aetna considers competitor trends in setting the unit price trend target for a market, because if Aetna believes other carriers will set a certain trend, Aetna may need to match it to remain competitive in that market. Finally, the provider contracts up for renewal during the year are reviewed to incorporate any increases included within those contracts in planning the trend target.

Each year, there is a single national unit price trend target, and each region sets a trend target at the local market level that contributes to the overall national trend target. The local market trend target includes both M/S and MH/SUD providers. In establishing and refreshing the AMFS, network teams aim to meet the unit price trend target. Because insurance premiums are generally set prospectively, this factor relies on actuarial judgment, as the unit price trend target for the year is set in advance. Aetna's actuaries examine the evidentiary standards described above to determine what overall trend target is needed to close any competitive gaps. Within an individual market, Aetna's network leadership have discretion to increase rates. As AMFS and provider contracts are finalized in the course of the year, Aetna tracks the newly-agreed rates to monitor whether the market is on track to meet the target or whether there will be a variance from it.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Provider type** refers to a professional provider's licensure and level of education.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies to M/S and MH/SUD benefits delivered in-network. All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. For both M/S and MH/SUD services, listed provider types are reimbursed at a percentage of the physician rate based on licensure.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***:

- CMS Medicare Claims Processing Manual, Chapter 12 – Physicians/Nonphysician Practitioners[1] includes reimbursement methodologies for physician assistant, nurse practitioner, clinical social worker, marriage and family therapist, and mental health counselor services reimbursed at a percentage of the physician rate.
- Aetna's payment policy N004: Non-Physician Providers Payment Policy documents the provider types and reimbursement percentages used in establishing reimbursement for covered services:

Aetna Reimburses Participating Providers at the Following Percentage of the AMFS		
	M/S Provider Types	**MH/SUD Provider Types**
100%	• Doctors	• Doctors (Psychiatrists or Addictionologist with MD or DO) • Clinical Psychologists
85%	• Certified Nurse Midwives • Clinical Nurse Specialists (e.g., Nurse Practitioner or Registered Nurse) • Physician Assistants	• Behavioral Health Nurse Practitioners • Behavioral Health Physician Assistants • Psychiatric Nurses
75%	• Audiologists • Genetic Counselors • Massage Therapists • Nutritionists • Registered Dieticians • Respiratory Therapists	• Certified Addiction Counselors • Clinical Social Workers • Drug and Alcohol Counselors • Licensed Professional Counselors • Marriage and Family Counselors • Pastoral Counselors • Psychoanalysts • Psychological Examiners

[1] The CMS Medicare Claims Processing Manual Chapter 12 is available online at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: In establishing or refreshing the preferred participating professional provider fee schedule (AMFS), the factors of service type and index rates are used together to align proposed reimbursement rates to procedure codes. The service type is represented by CPT or HCPCS codes, which are valued in the index rates, whether that index rate is based on Medicare CMS rates or another index rate. The proposed AMFS is then evaluated at the market level by each individual Aetna market. Market dynamics inform whether Aetna's Network Management and MEU adjust the proposed rate for the specific market. Once the rates are adjusted, the MH/SUD class rates are set to be equal to or higher than the M/S class rates. Finally, once the proposed rates are established, the rates are set based on a percentage of the final physician rate, for both M/S and MH/SUD practitioners, based on licensure.

(b) Factors for establishing or evaluating a proposed facility fee schedule

- **Scope and complexity of services** refers to the range of practice specialties, levels of care, and settings offered by the facility.

(a) ***How the factor is used to determine which benefits are subject to the NQTL:*** All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. This factor applies equally to M/S and MH/SUD benefits delivered in-network. The scope and complexity of the services provided by a facility, for both M/S and MH/SUD benefits, is a predicate consideration for the available reimbursement methodologies upon which a facility fee schedule may be based.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL:*** The evidentiary standards relied upon when applying this factor are the facility type and service type. The scope and complexity of services vary between different facility types. For example, inpatient facilities that must staff around-the-clock care are reimbursed differently from independent labs or radiology facilities. The service type refers to the codes that facilities submit on billing forms, as well as whether the services are inpatient or outpatient. The billing codes include CPT, HCPCS, and ICD-10 diagnosis codes, which are used in participating facility reimbursement. The AMA issues, updates, and maintains these clinically valid code sets to accurately reflect current clinical practice and innovation in medicine. Some service code definitions specify *per diem* (e.g., MH/SUD residential treatment facility

care) or case rate (e.g., infertility treatment), which may inform the reimbursement methodology and how these services are negotiated.

(c) ***If the factor depends on specific decisions made in the administration of benefits:*** This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor:*** There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Index rates** are third-party rates used as a benchmark in developing or evaluating a facility fee schedule and contracting with providers for the negotiated charges.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. This factor applies equally to M/S and MH/SUD benefits delivered in-network. Index rates, if applicable, are used as benchmarks to evaluate the preliminary facility fee schedule if the facility offers the initial fees, or to establish the preliminary facility fee schedule if Aetna offers the initial fees.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: In general, the evidentiary standard for this factor is the Medicare rate for the same service code. Medicare employs a number of different facility payment methodologies and rates for facility inpatient and outpatient services, for M/S and MH/SUD services. Medicare DRG payment methodology uses a diagnosis to value an all-inclusive payment for an inpatient stay, resulting in lower payment for conditions that are less resource-intensive to treat, and a higher payment for more severe conditions that require more intensive treatment. The RBRVS payment methodology, developed by CMS in consultation with the AMA, assigns RVUs to service codes to reflect the physician or other provider work involved, practice expense, and liability insurance each service code entails. CMS applies a conversion factor to the RVU and an adjustment for the geographic area to calculate the resulting RBRVS rate. Other Medicare-based pricing sources are used for services and supplies that do not fall under RBRVS. These are: DMEPOS (durable medical equipment, prosthetic, orthotic and supplies), PEN (parenteral and enteral nutrition), Clinical Lab Fee Schedule, and Medicare ASP (Average Sale Price). These Medicare-based rates are used as an index when developing or evaluating a facility fee schedule.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Competitive data:** Refers to what competitors pay the facility for the same services, to the extent that can be determined from publicly available information.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL:*** All benefits delivered in-network are subject to participating provider reimbursement. This factor applies equally to M/S and MH/SUD benefits delivered in-network. Aetna uses competitive data, when available, in evaluating a facility fee schedule to determine whether potential rates are competitive based on where the provider is located.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL:*** State All Payer Claims Databases are repositories of health care claims and encounter data filed in accordance with each state's data collection standards and processes. To the extent this data can be used as a benchmark to understand what rates are competitive in a given market, Aetna uses this competitive information to propose or evaluate a facility fee schedule. External consulting firm analyses of Aetna's discount position in the market compared to other carriers provide another basis for Aetna to examine what rates are competitive in a given market. These analyses are based on the bi-annual industry Uniform Discount Specification (UDS) process, in which Aetna and other carriers participate, to supply standardized claim data to consulting firms to allow for a uniform and comparable evaluation of health plan costs. The UDS is generally used by brokers to help plans compare carriers, but these analyses also provide insight into how Aetna's network discounts compare to other carriers.
    (c) ***If the factor depends on specific decisions made in the administration of benefits:*** This factor does not depend on specific decisions made in the administration of benefits.
    (d) ***Deviations or variations from a factor***: For MH/SUD facility services, there generally is not enough information in the All Payer Claims Databases to rely on this external competitive data. For MH/SUD facility services, the only competitive information Aetna often has available to rely upon in evaluating or proposing a fee schedule is information about what Aetna pays other similarly situated facilities.

- **Market dynamics** refers to the unique characteristics of a market, including supply and demand, the carrier's market penetration compared to other carriers and networks, and any other relevant characteristics specific to that market.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All benefits delivered in-network are subject to participating provider reimbursement. This factor applies to M/S and MH/SUD services equally. For M/S and MH/SUD services, market dynamics inform whether the initial fee schedule, whether proposed by the facility or Aetna, is adjusted for specific market considerations. The

assessment of market dynamics could also result in no adjustment to the proposed fee schedule.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that is relied upon when applying this factor is Aetna's Network Management's analysis of the market, including supply and demand, Aetna's market penetration compared to other carriers and network, and any other relevant characteristics specific to that market. Supply and demand refers to how many facilities there are in a particular geographic area who provide the same services, and how much need there is for those services among the membership, including whether the network adequacy standards are met (see Aetna's Network Adequacy NQTL Comparative Analysis). Market penetration refers to evaluation of how many plan members are in the market, which results in greater patient volume for network providers.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: For both M/S and MH/SUD services, the factor "scope and complexity of services" is considered first, because a facility's contract covers the variety of services available, and a contractual fee schedule must account for each service type that will be submitted for reimbursement by the facility. The factors of index rates and competitive data are used when available to evaluate whether the proposed fees are competitive within the market, where the information is available. As noted above, index rates and competitive data may not be available, such as for services that Medicare does not value, or where there is not sufficient relevant information in the All Payer Claim Databases. Additionally, the external consulting firm analyses may not provide useful information in a given fee schedule evaluation, because the discount information supplied may be outdated, given the lag time in the data collection and analysis process. Therefore, the factors of index rates and competitive data are weighted less than the factors of scope and complexity of services and market dynamics. Market dynamics is a factor considered in evaluating or proposing a facility fee schedule that considers influences specific to the facility's market and is generally considered after the factors of index rates and competitive data, but is weighted more heavily than those factors. These factors are equally applicable to both M/S and MH/SUD benefits.

(c) Factors for negotiating participating professional and facility reimbursement rates

- **Unit price trend target** refers to the percentage of the unit price by which the network determines it can adjust overall M/S and MH/SUD rates. The unit price trend target is an overall baseline for negotiations with providers.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered in-network are subject to participating provider reimbursement. The factor of unit price trend target applies equally to M/S and MH/SUD services. Aetna's MEU establishes the unit price trend target, and each network team has a goal of conducting overall contracting with providers in a way that allows them to achieve the trend target.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards that are relied upon when applying this factor are claim utilization data, current network rates, estimated competitor unit price trends, and the provider contracts up for renewal that year.

Using prior year claim utilization as a baseline, Aetna's MEU forecasts costs for future claim payments and determines how much the costs can increase while remaining competitive in the market from both a provider reimbursement and member premium perspective. Prior year claim utilization forms the baseline for what claim utilization to expect in the future. Current network rates are used to predict costs for forecasted claim utilization, forming the starting point from which rates may increase. Aetna considers competitor trends in setting the unit price trend target for a market, because if Aetna believes other carriers will set a certain trend, Aetna may need to match it to remain competitive in that market. Finally, the provider contracts up for renewal during the year are reviewed to incorporate any increases included within those contracts in planning the trend target.

Each year, there is a single national unit price trend target, and each region sets a trend target at the local market level that contributes to the overall national trend target. The local market trend target includes both M/S and MH/SUD providers. The network teams still negotiate with providers as needed to maintain an adequate network even if that means their trend target is exceeded. Because insurance premiums are generally set prospectively, this factor relies on actuarial judgment, as the unit price trend target for the year is set in advance. Aetna's actuaries examine the evidentiary standards described above to determine what overall trend target is needed to close any competitive gaps. Within an individual contract negotiation, Aetna's contract negotiators and network leadership have discretion to increase rates. As provider contracts are finalized in the course of the year, Aetna tracks the newly-agreed rates to monitor whether the market is on track to meet the target or whether there will be a variance from it.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Provider leverage,** or bargaining power, refers to a professional provider's ability to negotiate a rate higher than AMFS, and a facility's ability to negotiate higher rates.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: The factor of provider leverage applies to M/S and MH/SUD benefits equally. All benefits delivered in-network are subject to participating provider reimbursement. Both M/S and MH/SUD providers may negotiate rates other than the standard AMFS, and may engage in efforts to secure higher facility reimbursement rates. However, whether the plan is willing to pay the provider something above AMFS, or pay higher facility rates, depends on the provider's leverage. For both M/S and MH/SUD benefits, a provider's leverage drives whether and by how much a professional provider's final fee schedule differs from the AMFS and the development of a facility provider's fee schedule.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: In broad terms, provider leverage describes how much need there is for that provider in the network in relation to how much the network is prepared to pay that provider. A provider's leverage varies from one provider to the next, and even for the same provider it can vary from one contract negotiation to the next based on changes in the composition of the network and membership. While various evidentiary standards are set forth herein, they may not be applicable in all instances given the particular facts, circumstances and market dynamics at issue with respect to a given professional or facility provider. A large provider group that does not include the types of providers the network needs, or a large provider group that is located in an area without many Aetna members, would not have as much leverage as a smaller provider group comprised of needed specialists, or that serves a larger membership. Aetna's Network Management teams conduct contract negotiations, which are necessarily individualized to the circumstances of the particular contract negotiation. Generally, the evidentiary standards for this factor are the relative scarcity of the type of provider, whether the provider is part of a large health system or practice group that includes numerous specialties, plan sponsor demand and the number of members the provider serves, and the provider's participation with other carriers.

- The relative scarcity of the provider's specialty or area of focus, or a facility provider's licensure and type of services provided, is considered along with the number of providers of that specialty or subspecialty in the same geographic area, both in the Aetna network as well as overall. When the network needs a

provider specialty/focus or facility type to meet network standards or member demand, those provider types typically have more leverage than other provider types. Member needs or demand for specific provider types is based on evaluation of network availability standards, and out-of-network requests. The network availability and out-of-network utilization results are reviewed as part of Aetna's network adequacy analysis and may indicate which provider types may be beneficial in a specified market.

- Whether the provider is part of a large health system or practice group that includes numerous specialties may impact the provider's leverage. A group or health system with three or more specialty types will generally have more leverage than a group with one or two specialty types. However, this may not be true in all instances and is impacted by specific market needs.
- Plan sponsor demand is considered in determining a provider's leverage. This standard is based on recruitment requests through RFPs, disruption reports for providers leaving the network, and membership growth in specific markets.
- The number of members served by the provider is based upon the amount of Aetna membership in that area and the number of Aetna members the provider is treating on an out-of-network basis.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: The MEU establishes the unit price trend target that is used as a guardrail in individual provider negotiations, during which a provider's leverage influences the potential for increase in their fee schedule. The network teams still negotiate with providers as needed to maintain an adequate network even if that means exceeding the trend target. These factors are complementary and are weighted equally.

<u>Step 4</u>: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

*This Step 4 demonstrates that, under the terms of the plan, **as written**, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts: **(1)** design and **(2)** application. Within each such discussion, this Step 4 addresses **(a)** documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification, **(b)** in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL, **(c)** documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and **(d)** as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, participating provider reimbursement applies to all M/S and MH/SUD services provided in-network. Accordingly, participating provider reimbursement applies to the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient-office; 3) in-network outpatient-all other; and 4) emergency. As noted in Step 2, Part 1, the factors used in designing participating provider reimbursement are 1) cost management and 2) market competitiveness. Cost management and market competitiveness are general design factors and provide a basis and rationale underlying Aetna's participating provider reimbursement for M/S and MH/SUD services. These design factors do not distinguish between, and are agnostically applied to, both M/S and MH/SUD benefits.

Cost management, as defined in Step 2, Part 1 above, is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD benefits. Cost management as a design factor is further articulated in CVS Health public filings, which acknowledge that failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (see, e.g., Form 10-K at page 34: "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). In addition, Aetna's **Network Policy 281: Participating Provider Reimbursement P&P** which applies to both M/S and MH/SUD benefits, outlines these considerations and notes

that participating provider reimbursement is designed to achieve the goals of cost management and market competitiveness. Aetna's participating provider reimbursement strategy seeks to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders, including through contracting with providers for appropriate agreed-upon rates. Additionally, Aetna seeks to maintain market competitiveness by achieving total health care cost rates that are competitive with the total health care cost rates for similar products issued by others in the market, to achieve premium pricing required to compete effectively and develop and maintain attractive networks with high-quality providers. Together, these factors underlie Aetna's strategy to appropriately reimburse participating providers in a manner that fosters a strong provider network that is attractive to members, providers, and health plans, while promoting affordable premiums and management of overall risk to the health plan. The factors of cost management and market competitiveness are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the application of participating provider reimbursement. As written, the processes, strategies, evidentiary standards or other factors used in designing participating provider reimbursement with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing the NQTL with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, Part 2, participating provider reimbursement applies to all M/S and MH/SUD services provided in-network. Accordingly, participating provider reimbursement applies to the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient-office; 3) in-network outpatient-all other; and 4) emergency. As noted in Step 2, Part 2, different factors are applied in the context of participating provider reimbursement for: (a) establishing and refreshing the standard participating professional provider fee schedule, the AFMS; (b) establishing or evaluating a proposed facility fee schedule; and (c) negotiating participating professional and facility reimbursement rates. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying participating provider reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying the NQTL to M/S benefits in the applicable benefit classifications.

(a) Establishing and refreshing the Aetna preferred professional provider fee schedule (AMFS)

As set forth in Step 2, Part 2, the factors used in the application of participating provider reimbursement to establish and refresh the preferred professional provider fee schedule are: 1)

index rates; 2) service type; 3) market dynamics; 4) unit price trend target; and 5) provider type. This section demonstrates that these factors are applied, as written, comparably and no more stringently to MH/SUD benefits than they are to M/S benefits.

Aetna **Network Policy 280: Aetna Market Fee Schedule Rate Development Policy & Procedure – Non-Facility Providers** ("AMFS Policy") outlines how Aetna's MEU and Network teams establish the AMFS rates for participating professional M/S and MH/SUD providers. The AMFS Policy describes how the factors of index rates, also referred to as pricing sources, and provider type, also referred to as specialty tiering, are used by Aetna's MEU to propose new or refreshed AMFS rates for service codes, for M/S and MH/SUD services. The AMFS Policy lists the pricing sources and hierarchy for developing the M/S and MH/SUD AMFS. For M/S services, the hierarchy is:

- Medicare-based pricing sources including RBRVS, DMEPOS, PEN, and Clinical Lab Fee Schedule; and
- Non-Medicare based pricing sources, including GAP, DART, National Carveouts, and other pricing sources specific to immunizations and durable medical equipment.

There is a separate pricing source hierarchy for MH/SUD services, which omits the pricing sources that do not apply to MH/SUD services. For MH/SUD services, the hierarchy is:

- Medicare-based pricing sources, which is limited to RBRVS; and
- Non-Medicare pricing sources, including GAP, DART, and National Carveouts.

These pricing sources are used as index rates and are discussed in Step 3, Part 2. These are the pricing sources used by MEU as a basis to propose M/S and MH/SUD AMFS rates. Additionally, per the AMFS Policy, Network teams classify service codes as Medical class or Behavioral Health (BH) class. Network teams classify codes most commonly billed by M/S providers but which may also be billed by MH/SUD providers as Medical class, and codes most commonly billed by MH/SUD providers but which may also be billed by M/S providers as BH class. After MEU proposes AMFS rates for a given market, Network Management evaluates the same and may request adjustments to these rates based on the market dynamics, which is a factor discussed in Step 3, Part 2. Pursuant to the AMFS Policy, for service types that are billed both by M/S and MH/SUD providers, after the rate for M/S providers is determined, the rate for the same service for MH/SUD providers is set at or above the M/S rate. The AMFS Policy requires an audit prior to loading these rates for use in claim processing, which checks for accuracy of various items, including that the MH/SUD rates are set at or above the M/S rate for the same service. Finally, the AMFS Policy includes the procedure for specialty tiering and place of service, appliable to both M/S and MH/SUD services. The place of service follows the Medicare-recognized place of service, providing separate rates for professional provider office-based and non-office, or facility, based services. As with Medicare rates, the facility-based rates are generally lower than office-based rates. The factor of provider type is applied through the specialty tiering, whereby both M/S and MH/SUD practitioner rates are a percentage of the rate for a specific service code based on the provider's licensure, as further described in the AMFS Policy and Aetna Policy N004.

Aetna Policy **N004: Non-Physician Providers Payment Policy** defines the reimbursement rate for non-physician providers. This policy defines non-physician providers for both M/S and MH/SUD as a health care professional who is not a Medical Doctor (MD) or a Doctor of Osteopathic Medicine (DO). As shown below, for both M/S and MH/SUD, clinical nurse specialists and physician assistants are reimbursed at 85% of the physician's rate. For both M/S and MH/SUD, other masters-level provider types are reimbursed at 75% of the physician's rate. Pursuant to this policy, based on the provider type and licensure, the following providers are reimbursed at the following percentage of the physician rate for covered services:

Aetna Reimburses Participating Providers at the Following Percentage of the AMFS for Covered Services:		
	M/S Provider Types	**MH/SUD Provider Types**
100%	• Doctors	• Doctors (Psychiatrists or Addictionologist with MD or DO) • Clinical Psychologists
85%	• Certified Nurse Midwives • Clinical Nurse Specialists (e.g., Nurse Practitioner or Registered Nurse) • Physician Assistants	• Behavioral Health Nurse Practitioners • Behavioral Health Physician Assistants • Psychiatric Nurses
75%	• Audiologists • Genetic Counselors • Massage Therapists • Nutritionists • Registered Dieticians • Respiratory Therapists	• Certified Addiction Counselors • Clinical Social Workers • Drug and Alcohol Counselors • Licensed Professional Counselors • Marriage and Family Counselors • Pastoral Counselors • Psychoanalysts • Psychological Examiners

The AMFS for each market is periodically refreshed, as determined by Aetna network leadership at the market level. When refreshing the AMFS, or considering whether to refresh the AMFS, each network team will consider the unit price trend target. Each year, Aetna's MEU sets a single national unit price trend target, and each region sets a trend target at the local market level that contributes to the overall national trend target. The local market trend target includes both M/S and MH/SUD provider rates and is inclusive of refreshing the AMFS rates (if applicable) and individualized contract negotiations with professional providers and facilities. In establishing and refreshing the AMFS, network teams aim to meet the unit price trend target. Within an individual market, Aetna's network leadership have discretion to increase rates. As AMFS and provider contracts are finalized in the course of the year, Aetna tracks the new rates to monitor whether the market is on track to meet the target. Per the AMFS Policy, if the network decides to refresh AMFS rates for a given market, for service types that are billed both by M/S and MH/SUD providers,

after the rate for M/S providers is determined, the rate for the same service for MH/SUD providers is set at or above the M/S rate.

In sum, Aetna sets the standard AMFS rates for M/S and MH/SUD participating professional providers using the factors of 1) index rates; 2) service type; 3) market dynamics; 4) unit price trend target; and 5) provider type, which apply to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. There are no differences in how these factors are applied to MH/SUD benefits compared to M/S benefits, as written, that result in MH/SUD benefits being treated incomparably or more stringently. Aetna maintains one AMFS Policy and one Non-Physician Providers Payment Policy that apply to both M/S and MH/SUD benefits. The pricing sources hierarchy used for index rates for M/S services and MH/SUD services follows the same hierarchy, though there are some different sources within the hierarchy that are applicable to M/S and MH/SUD services. Importantly, when setting AMFS rates, for services that can be billed by both M/S and MH/SUD providers, the rate for the MH/SUD providers is always set at or higher than the rate for M/S providers. Accordingly, Aetna's analysis of the "as written" material used to apply participating provider reimbursement and establish and refresh the standard AMFS rates, shows that these factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(b) Establishing or evaluating a proposed facility fee schedule

As set forth in Step 2, Part 2, the factors used in the application of participating provider reimbursement to establish or evaluate a proposed facility fee schedule are: 1) scope and complexity of services; 2) index rates; 3) competitive data; and 4) market dynamics. This section demonstrates that the factors are applied, as written, comparably and not more stringently to MH/SUD benefits than they are to M/S benefits.

Aetna's **Network Policy 281: Participating Provider Reimbursement Policy & Procedure** outlines the factors used in establishing or evaluating a proposed facility fee schedule and demonstrates that reimbursement strategies are consistently applied across M/S and MH/SUD benefit classifications. As noted in this policy, there is no standard fee schedule for M/S or MH/SUD facility providers, and each facility fee schedule is negotiated individually. The policy, however, memorializes a general framework and the factors considered in evaluating a proposed facility fee schedule, applicable to both M/S and MH/SUD facility providers: 1) scope and complexity of services; 2) index rates; 3) competitive data; and 4) market dynamics. For both M/S and MH/SUD, scope and complexity of services refers to the range of practice specialties, levels of care, and settings offered by the facility. For both M/S and MH/SUD, index rates are third-party rates used as a benchmark in developing or evaluating a facility fee schedule and contracting with providers for negotiated charges. Competitive data refers to what competitors pay a facility for the same services, to the extent that can be determined from publicly available information, for both

M/S and MH/SUD facilities. Finally, market dynamics, for both M/S and MH/SUD, refers to the unique characteristics of the market, including supply and demand, a carrier's market penetration compared to other carriers and networks, and any other relevant characteristics specific to that market.

Aetna's policy **AETPENO-072113: Contracting Guidelines Policy** outlines the requirement for following contracting guidelines when contracting with providers for M/S and MH/SUD services, and sets forth various requirements for provider contracts, including with respect to reimbursement. Aetna's Network team develops contracting guidelines to indicate preferred, acceptable, discouraged, and unacceptable payment methodologies, identify alternatives to preferred payment methodologies, and ensure proper consideration of discouraged items. As noted above, there is no standard fee schedule for M/S or MH/SUD facilities, but the contracting guidelines identify the preferred payment methodology for each facility type, which reflects the scope and complexity of the services.

For example, for inpatient hospital services, the preferred payment methodology for M/S is room and board level of care as a *per diem*, and for MH/SUD inpatient services, *per diem* for each service level. Further, an acceptable payment methodology for M/S is DRG, and an acceptable payment methodology for MH/SUD is a case rate, as commercial plans typically do not use DRG billing for MH/SUD services, and the MH/SUD service codes facilities are contracted for are *per diem* codes. For both M/S and MH/SUD inpatient services, an unacceptable payment methodology is to pay services at a percentage of the billed amount without certain additional measures in place. As to other inpatient services, as written in the contracting guidelines, the preferred reimbursement methodology for MH/SUD inpatient residential treatment facility is *per diem*, which is the same preferred reimbursement methodology for M/S skilled nursing facilities.

Pursuant to the Contracting Guidelines Policy, network teams must obtain appropriate approvals based on whether the provider contract includes preferred, acceptable, discouraged, or unacceptable contract language. Ultimately, the reimbursement methodology used in a contract is the result of the individualized negotiations on a facility-by-facility basis. Aside from the selection of a payment methodology to provide the basis of a facility fee schedule, the factors of index rates, competitive data, and market dynamics are further applied with respect to both M/S and MH/SUD services to reach ultimately agreed-upon rates. Aetna's analysis of the "as written" material used to apply participating provider reimbursement and evaluate facility fee schedules, shows that the factors, evidentiary standards, and sources (to the extent they are addressed in written materials) are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

(c) Factors for negotiating participating professional and facility reimbursement rates

As set forth in Step 2, Part 2, the factors for negotiating participating professional and facility reimbursement rates are: 1) unit price trend target and 2) provider leverage. This section

demonstrates that the factors are applied, as written, comparably and not more stringently to MH/SUD benefits than they are to M/S benefits.

Aetna's **Network Policy 281: Participating Provider Reimbursement Policy & Procedure** outlines the factors used in negotiating participating professional and facility reimbursement rates and demonstrates that reimbursement strategies are consistently applied across M/S and MH/SUD benefit classifications. Within an individual contract negotiation, Aetna's contract negotiators and network leadership have discretion to increase rates for both M/S and MH/SUD providers. As noted in the Policy, there is a single, national, unit price trend target that includes both M/S and MH/SUD provider rate increases. Aetna's MEU establishes the unit price trend target using the evidentiary standards discussed in this comparative analysis, and which are outlined in Network Policy 281. The Policy describes how the unit price trend target is derived and how the Network teams track agreed upon rates to monitor whether the market is on track to meet the target or whether there will be a variance from it. The Policy further provides that the local market network teams negotiate with M/S and MH/SUD providers as needed to maintain an adequate network, even if that means the unit price trend target is exceeded.

The Policy also describes the factor of provider leverage, including consideration of various elements of provider leverage, which can include, the relative scarcity of the provider's specialty or area of focus; whether the provider is part of a large health system or practice group that includes numerous specialties; plan sponsor demand; and the number of members served by the provider. As discussed in Step 3, Part 2, and as reflected in the Policy, as a general framework, each of these evidentiary standards and sources is equally applicable to M/S and MH/SUD provider negotiations. The policy notes that, necessarily, a provider's leverage varies from one provider to the next, and even for the same provider it can vary from one contract negotiation to the next based on changes in the composition of the network, membership, and other characteristics. However, these general considerations are the same for M/S and MH/SUD providers.

Aetna's analysis of the "as written" material, Network Policy 281: Participating Provider Reimbursement P&P, used to apply participating provider reimbursement in negotiating professional and facility reimbursement rates shows that the factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and not more stringently applied to MH/SUD services.

Summary

The factors for establishing and refreshing Aetna's standard professional provider fee schedule, establishing or evaluating a proposed facility fee schedule, and negotiating participating professional and facility reimbursement rates apply equally to M/S and MH/SUD providers. There are no differences in how these factors are applied to MH/SUD benefits compared to M/S benefits, as written, that result in MH/SUD benefits being treated incomparably or more stringently. As written, the processes, strategies, evidentiary standards and other factors used in applying

participating provider reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying the NQTL to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137-1(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

As noted in Step 1, Part 2, participating provider reimbursement applies to all M/S and MH/SUD services provided in-network. Accordingly, participating provider reimbursement applies to the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient-office; 3) in-network outpatient-all other; and 4) emergency. In conducting this analysis, Aetna evaluates, whether, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying the NQTL with respect to M/S benefits. For participating provider reimbursement, Aetna reviews the amount eligible for payment to participating providers as one measure that can evaluate whether participating provider reimbursement is applied comparably, and not more stringently, to MH/SUD services as compared to M/S services. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying participating reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to M/S benefits.

For professional providers, there are two main steps for setting network professional provider reimbursement, which are the same for M/S and MH/SUD services: 1) developing and refreshing the AMFS rates which are the baseline for contracting with professional providers and 2) negotiating reimbursement rates with providers. The factors, strategy, processes and evidentiary standards for determining reimbursement for MH/SUD professional providers are comparable to M/S professional providers, inasmuch as the negotiated charges begin with the AMFS rates, but are ultimately subject to individualized negotiations between Aetna and the provider. As described in this analysis, Aetna establishes a standard fee schedule, AMFS, for use in contracting with professional providers. Review of the standard rates for M/S and MH/SUD providers for shared codes can provide a basis to evaluate comparability and stringency. In operation, all shared codes

(codes that can be billed by both M/S and MH/SUD providers) for MH/SUD providers are set at the same rate as or higher than the rate for M/S providers. For illustrative purposes, the below chart represents the standard reimbursement rate data for Aetna's insured business for participating M/S and MH/SUD office-based providers in the Richmond Virginia market, selected as an example Aetna market. As set forth above, AMFS is set at the geographic market level, and the Richmond VA market is selected as an example because it is a mid-range price market.

The below chart reflects reimbursement rate data for 2026 for codes shared by M/S and MH/SUD office-based providers. This chart shows the four most frequently billed shared codes, meaning these codes may be billed by both M/S and MH/SUD providers, as a way to compare reimbursement rates for M/S and MH/SUD physicians for the same code. The four most frequently billed evaluation and management codes, which are billable by physicians, are:

- **99203**: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.
- **99204**: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.
- **99213**: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.
- **99214**: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.

VA (Richmond) Rates for Office-Based Physicians 07/01/25-06/30/26		
Service Code	**M/S AMFS**	**MH/SUD AMFS**
99203	$106.53	$106.53
99204	$161.86	$161.86
99213	$73.07	$73.07
99214	$107.03	$107.03

This data shows that, in operation, Aetna's standard M/S and MH/SUD office-based physician rates are the same for each CPT code. The physician rate applies to MH/SUD physicians, which are psychiatrists and addictionologists, and the M/S physician rate applies for all M/S primary care and specialist physician types.

Regarding facility providers, the factors, strategy, processes and evidentiary standards for determining reimbursement for MH/SUD facility providers are comparable to M/S facility providers, inasmuch as the negotiated charges are ultimately subject to individualized negotiations based upon the same factors set forth above in Step 2, as between Aetna and the facility. Notwithstanding the comparable processes, most MH/SUD facilities are paid on a *per diem* basis, whereas M/S facilities are paid by a wide variety of reimbursement methodologies including DRGs, *per diem*, percent of Medicare, and percent of billed charges. This difference is due to the fact that many MH/SUD billing codes describe daily, or *per diem*, services. Also, the structures and scope of services of MH/SUD facilities are simpler than those of M/S facilities which often have multiple specialties and locations and provide a wide range of service types; multiple reimbursement methodologies are therefore more common within a single M/S facility contract.

A comparison of reimbursement rates between facilities that are paid using different reimbursement methodology(ies) such as DRG versus *per diem*, and for different services, is not possible because they are too disparate to allow comparison. Nevertheless, there are some professional services that can be billed by both M/S and MH/SUD facility-based providers, and under some facility contracts those may be reimbursed on a fee for service basis using AMFS. This is demonstrated by reviewing AMFS rates for the four most frequently billed shared codes, as defined above, again using the Richmond VA market as an example market. This in-operation data for the Virginia market also shows that the standard M/S and MH/SUD rates are the same for each CPT code.

VA (Richmond) Rates for Facility-Based Physicians 07/01/25 - 06/30/26		
Service Code	**M/S AMFS**	**MH/SUD AMFS**
99203	$75.19	$75.19
99204	$127.38	$127.38
99213	$50.43	$50.43
99214	$77.78	$77.78

This evaluation of participating provider reimbursement demonstrates that the processes, strategies, evidentiary standards, and other factors used to design and apply the NQTL are applied comparably to M/S and MH/SUD benefits. The process for setting AMFS rates is conducted in a comparable manner for M/S and MH/SUD, in operation, resulting in identical reimbursement for the same service codes. For both facilities, and for professional providers whose contracts deviate from AMFS rates, the factors, strategy, processes and evidentiary standards for determining

reimbursement for MH/SUD providers are comparable to M/S providers, inasmuch as the negotiated charges are ultimately subject to individualized negotiations, based upon the same factors of unit cost trend target and provider leverage, as between Aetna and the facility. Even though Aetna's factors, processes and evidentiary standards for determining MH/SUD rates are comparable and not more stringent than for M/S rates, the final negotiated charges will not reflect identical or more favorable MH/SUD rates in every instance. Providers are free to negotiate rates different from the proposed fee schedule, and their bargaining power may result in negotiated charges that vary among providers.

Taken together and in the aggregate, the analysis conducted demonstrates that in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying participating provider reimbursement for MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying participating provider reimbursement for M/S benefits.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

Participating provider reimbursement is payment to in-network providers for covered services provided to members; it represents the amount a network provider has agreed to accept or that Aetna has agreed to pay. As demonstrated in Step 1, participating provider reimbursement applies to all M/S and MH/SUD benefits delivered in-network, including the benefit classifications of 1) in-network inpatient; 2) in-network outpatient-office; 3) in-network outpatient-all other; and

4) emergency. Step 2 identified the factors used to establish and refresh Aetna's preferred professional provider fee schedule (AMFS), to establish or evaluate a proposed facility fee schedule, and to negotiate participating professional and facility reimbursement rates. Step 3 explained the evidentiary standards and sources for those factors. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD network providers and concluded that there are no written differences in that application that results in any MH/SUD providers or benefits being treated more stringently than, or incomparably to, M/S providers or services. Finally, Step 5 demonstrated that, in operation, MH/SUD participating provider reimbursement rates are established in a comparable and no more stringent manner.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of CFR 146.136(c)(4). As demonstrated in Steps 1-5, Aetna applies the same factors, evidentiary standards, and sources, in designing and applying participating provider reimbursement with respect to M/S and MH/SUD providers. The design factors noted in Step 2, Part 1 are 1) cost management and 2) market competitiveness. These factors apply equally and agnostically as general design factors with respect to M/S and MH/SUD benefits, with the goal of achieving total health care cost rates that are competitive with the total health care cost rates for similar products issued by third parties in the market so as to achieve premium pricing required to compete effectively, attract and retain providers in the network, and drive membership growth. The application factors and evidentiary standards for establishing and/or refreshing the standard fee schedule (AMFS) for professional providers are used in the same way for M/S and MH/SUD practitioners. Aetna maintains and applies the same written policy and procedure to setting AMFS rates for both M/S and MH/SUD benefits. However, notably, when setting AMFS rates, for services that can be billed by both M/S and MH/SUD providers, the rate for the MH/SUD providers is always set at or higher than the rate for M/S providers. While there is no preferred or standard facility fee schedule for M/S or MH/SUD facilities, the application factors and evidentiary standards to establish or evaluate a proposed facility provider fee schedule are used in a comparable manner for M/S and MH/SUD facility providers. Further, Aetna maintains and applies the same written policies outlining applicable processes and contracting guidelines for M/S and MH/SUD services. For facilities, and for professional providers whose contracts deviate from AMFS rates, the factors, evidentiary standards, and sources for determining reimbursement for MH/SUD providers are comparable to M/S providers, inasmuch as the negotiated charges are ultimately subject to individualized negotiations, based upon the same factors of unit cost trend target and provider leverage, as between Aetna and the provider. For the written materials applicable to participating provider reimbursement discussed herein, there are no differences in how these factors are applied to MH/SUD benefits compared to M/S benefits, as written, that result in MH/SUD benefits being treated incomparably or more stringently.

As further demonstrated in Step 5, in operation, participating facility and professional provider reimbursement is determined in a comparable manner for both MH/SUD and M/S benefits. An in-operation review of participating provider reimbursement shows that MH/SUD

reimbursement rates are equal to M/S reimbursement rates for the same services. Aetna's "in operation" review shows that those factors and the related evidentiary standards are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply participating provider reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying participating provider reimbursement to M/S benefits across the applicable benefit classifications. Based upon the foregoing, Aetna concludes that the participating provider reimbursement NQTL is applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Executive Director, Medical Economics Unit • Executive Director, Network Management • Lead Director, Network Management

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Nonquantitative Treatment Limitation Comparative Analysis:

NON-PARTICIPATING PROVIDER REIMBURSEMENT

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 includes a description of the NQTL in two Parts: ***(1)*** *an identification and description of non-participating provider reimbursement and* ***(2)*** *an identification of all mental health/substance use disorder (MH/SUD) and medical/surgical (M/S) and benefits to which non-participating provider reimbursement applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Non-Participating Provider Reimbursement [45 CFR 146.137(c)(1)(i)]

Non-participating provider reimbursement is payment to out-of-network providers for covered services provided to members. The method for determining the reimbursement amount is defined in the certificate of coverage for each plan and is always the same for MH/SUD and M/S services. The following materials describe non-participating provider reimbursement:

1. Plan Documents

The member's certificate of coverage describes how out-of-network (OON) providers (i.e., non-participating providers) are reimbursed, and how Aetna manages the plan according to various internal policies and federal and state laws and regulations. Aetna's standard certificate of coverage language is below, which uses brackets to indicate variable plan language. The actual certificate members receive shows the plan coverage, which depends on applicable state law and plan elections. The plan's individual rate will be displayed in place of the bracketed range.

Certificate of Coverage – VA AL HCOC 14

Allowable amount

This is the amount of [an **out-of-network [provider's]] [**a **[provider's]**] charge that is eligible for coverage. You are responsible for all charges above this amount. The **allowable amount** depends on the geographic area where you get the service or supply.

[Allowable amount doesn't apply to involuntary services. These are services or supplies that are:

- Provided at a network facility by an **out-of-network [provider]**
- Not available from a **network [provider]**
- An **emergency service]**

The table below shows the method for calculating the **allowable amount** for specific services or supplies:

Service or supply:	**Allowable amount is based on:**
Professional services and other services or supplies not mentioned below	[Reasonable amount rate] [[50%-400%] of Medicare allowed rate]
Services of **hospitals** and other facilities	[Reasonable amount rate] [[50%-400%] of Medicare allowed rate]

Important note:
See *Special terms used* below, for a description of what the **allowable amount** is based on. If the **[provider]** bills less than the amount calculated using a method above, the **allowable amount** is what the **[provider]** bills.

[If your ID card displays the National Advantage Program (NAP) logo, your cost share may be lower when you get care from a NAP **[provider]**. [These are **out-of-network [providers]** and third party vendors who have contracts with us but are not **network [providers]**. When you get care from a NAP **[provider]**, your out-of-network cost share applies. Claims for services received from a NAP **[provider]** and paid at the NAP contracted rate are not subject to the federal surprise bill law.] [Contact us or the [policyholder] for more information.]]

Special terms used:

- [Facility charge review (FCR) rate is an amount that we determine is enough to cover the facility **[provider's]** estimated costs for the service and leave the **[provider]** with a reasonable profit. This means for:
  - **Hospitals** and other facilities that report costs or cost to charge ratios to The Centers for Medicare & Medicaid Services (CMS), the FCR rate is based on what the facilities report to CMS
  - Facilities that don't report costs or cost to charge ratios to CMS, the FCR rate is based on a statewide average of these facilities

  We may adjust the formula as needed to maintain the reasonableness of the **allowable amount**. For example, we may make an adjustment if we determine that in a state the charges of a specific type of facility are much higher than charges of facilities that report to CMS.]
- Geographic area is normally based using the first three digits of a zip code. If we believe we need more data for a particular service or supply, we may base rates on a wider geographic area such as the entire state.
- [Medicare allowed rates are the rates CMS establishes for services and supplies provided to Medicare enrollees without taking into account adjustments for specific **[provider]** performance. We update our system with revised rates within 180 days of receiving them from CMS. If Medicare doesn't have a rate, we use one or more of the items below to determine the rate for a service or supply:
  - The method CMS uses to set Medicare rates
  - How much other **[providers]** charge or accept as payment
  - How much work it takes to perform a service
  - Other things as needed to decide what rate is reasonable

  We may make the following exceptions:

- For inpatient services, our rate may exclude amounts CMS allows for operating Indirect Medical Education (IME) and Direct Graduate Medical Education (DGME) programs
- Our rate may exclude other payments that CMS may make directly to **hospitals** or other **[providers]** and backdated adjustments
- For anesthesia, our rate may be [at least 100%-350%] of the rate CMS establishes
- For lab, our rate may be [5%-75%] of the rate CMS establishes
- For DME, our rate may be [25%-75%] of the rate CMS establishes

When the **allowable amount** is based on a percentage of the Medicare allowed rate, it is not affected by adjustments or incentives given to **[providers]** under Medicare programs.]

- [Prevailing charge rate is the [50th-95th] percentile value reported in a database prepared by FAIR Health®, a non-profit company. FAIR Health may change these periodically. We update our systems within 180 days of receiving them from FAIR Health. If the database becomes unavailable, we may substitute a different, comparable database. If the alternate data source doesn't contain a value for a service or supply, we will base the **allowable amount** on the Medicare allowed rate.]

[Reasonable amount rate means your plan has established a rate amount as follows:

[**Service or supply:**	**Reasonable amount rate is:**
Professional services	[50th-95th] percentile value reported in a database prepared by FAIR Health
Inpatient and outpatient **hospital** charges	[[50%-500%] of Medicare allowed rate] [The FCR rate] [What the **[provider]** bills]
Inpatient and outpatient charges that are not from a **hospital**	[[50%-500%] of Medicare allowed rate] [The FCR rate] [What the **[provider]** bills]

…

(a) Our reimbursement policies

[We have the right to apply our reimbursement policies to all out-of-network services including involuntary services.] [We have the right to apply our reimbursement policies to all services.] This may affect the **allowable amount**. When we do this, we consider:

- The length and difficulty of a service
- Whether additional expenses are needed, when multiple procedures are billed at the same time
- Whether an assistant surgeon is needed
- If follow up care is included
- Whether other conditions change or make a service unique
- Whether any of the services described by a claim line are part of or related to the primary service provided, when a charge includes more than one claim line
- The educational level, licensure or length of training of the **[provider]**

We base our reimbursement policies on our review of:

- CMS National Correct Coding Initiative (NCCI) and other external materials that say what billing and coding practices are and aren't appropriate
- Generally accepted standards of medical and dental practice
- The views of **[physicians]** and dentists practicing in relevant clinical areas

We use commercial software to administer some of these policies. Policies may differ for professional services and facility services.

These reimbursement policies will comply with Virginia state law.

Get the most from your benefits:

We have online tools to help you decide whether to get care and if so, where. Log in to your member website. The website contains additional information that can help you determine the cost of a service or supply.]

[Balance billing protection for out-of-network services

You are protected from balance billing by an **out-of-network [provider]** for certain services.

(b) Our reimbursement policies

[We have the right to apply our reimbursement policies to all out-of-network services including involuntary services.] [We have the right to apply our reimbursement policies to all services.] This may affect the **allowable amount**. When we do this, we consider:

- The length and difficulty of a service
- Whether additional expenses are needed, when multiple procedures are billed at the same time
- Whether an assistant surgeon is needed
- If follow up care is included
- Whether other conditions change or make a service unique
- Whether any of the services described by a claim line are part of or related to the primary service provided, when a charge includes more than one claim line
- The educational level, licensure or length of training of the **[provider]**

We base our reimbursement policies on our review of:

- CMS National Correct Coding Initiative (NCCI) and other external materials that say what billing and coding practices are and aren't appropriate
- Generally accepted standards of medical and dental practice
- The views of **[physicians]** and dentists practicing in relevant clinical areas

We use commercial software to administer some of these policies. Policies may differ for professional services and facility services.

These reimbursement policies will comply with Virginia state law.

Get the most from your benefits:
We have online tools to help you decide whether to get care and if so, where. Log in to your member website. The website contains additional information that can help you determine the cost of a service or supply.]

[Balance billing protection for out-of-network services

You are protected from balance billing by an **out-of-network [provider]** for certain services.

Surprise bill

There may be times when you unknowingly receive services or don't consent to receive services from an **out-of-network [provider]**, even when you try to stay in the network for your **covered services**. You may get a bill at the out-of-network rate that you didn't expect. This is called a surprise bill.

An **out-of-network [provider]** can't balance bill or attempt to collect costs from you that exceed your in-network cost-sharing requirement, such as **deductibles**, **copayments** and **coinsurance** for the following services:

- **Emergency services** provided by an **out-of-network [provider]** and ancillary services initiated from your **emergency services**
- Non-emergency services provided by an **out-of-network [provider]** at an in-network facility, except when the **out-of-network [provider]** has given you the following:
  - The out-of-network notice for your signature
  - The estimated charges for the items and services
  - Notice that the **[provider]** is an **out-of-network [provider]**
- Out-of-network air ambulance services

The **out-of-network [provider]** must get your consent to be treated and balance billed by them.

Ancillary services mean any professional services including:

- Items and services related to emergency medicine
- Anesthesiology
- Hospitalist services
- Laboratory services
- Neonatology
- Pathology
- Radiology
- Services provided by an **out-of-network [provider]** because there was no **network [provider]** available to perform the service

A facility in this instance means an institution providing health care related services, or a health care setting. This includes the following:

- **Hospitals** and other licensed inpatient centers

- Ambulatory surgical or treatment centers
- **Skilled nursing facilities**
- **Residential treatment facilities**
- Diagnostic, laboratory, and imaging centers
- Rehabilitation facilities
- Other therapeutic health settings

A surprise bill claim is paid based on the median contracted rate for all plans offered by us in the same insurance market for the same or similar item or service that is all of the following:

- Provided by a **[provider]** in the same or similar specialty or facility of the same or similar facility type
- Provided in the geographic region in which the item or service is furnished

The median contracted rate is subject to additional adjustments as specified in federal regulations.

Any cost share paid with respect to the items and services will apply toward your in-network **deductible** and **maximum out-of-pocket limit** if you have one.

It is not a surprise bill when you knowingly choose to go out-of-network and have signed a consent notice for these services. In this case, you are responsible for all charges.

You may request external review if you want to know if the federal surprise bill law applies to your situation.

If you receive a surprise bill or have any questions about what a surprise bill is, contact us.

2. Policies and Procedures

The following Aetna policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address non-participating provider reimbursement:

- **Nonparticipating Provider Compensation (Pricing) Claim Processing Instructions and Policy:** The Nonparticipating Provider Compensation Claim Processing Instructions and Policy applies to both M/S and MH/SUD providers. It includes instructions for processing non-participating provider claims and details each step of the reimbursement amount hierarchy.
- **N004: Non-Physician Providers Payment Policy** addresses the reimbursement rate for specific M/S and MH/SUD non-physician providers. A non-physician provider is defined as a healthcare professional who is not a medical doctor or Doctor of Osteopathic Medicine. Non-physicians are also known as non-physician practitioners (NPPs) or non-physician health providers.
- **AETPENO-071143: 157-Non-Par National Default Fee Schedule:** This policy applies to MH/SUD and M/S providers, and documents the requirements related to timing and content of Aetna's National Non-Par Default Fee Schedule, as maintained in the claim processing system.
- **NCS 512: Non-Participating Provider Requests for In-Network Benefits P&P:** This policy outlines handling MH/SUD and M/S non-participating provider coverage requests during the precertification process, including referrals for single case contracting.
- **AETPENO-071699: 146-Single Case Letters of Agreement:** This policy defines the process for single case contracting, a/k/a executing a Letter of Agreement, and applies to M/S and MH/SUD providers.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii);] and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Benefits and Classification

The M/S and MH/SUD services described below are included in the **out-of-network inpatient** benefit classification, the **out-of-network outpatient office** and **out-of-network outpatient all other** subclassifications, and the **emergency** benefit classification.

Benefit Classifications to which NQTL Applies: ✔ **OON IP** ✔ **OON OV** ✔ **OON OP AO** ✔ **Emergency**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
All M/S benefits delivered out-of-network	All MH/SUD benefits delivered out-of-network

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146-137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of non-participating provider reimbursement. Each subpart includes:****(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to non-participating provider reimbursement, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL, non-participating provider reimbursement:

Factor	Applicable to M/S	Applicable to MH/SUD
Cost management	✓	✓
The voluntary or involuntary nature of the OON service	✓	✓

- **Cost management** is a **factor** and a **strategy** used to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care to policyholders. Cost management is an industry-employed practice of managing the costs of medical claims by optimizing utilization of services, contracting with providers for agreed-upon rates, reimbursing non-participating providers fairly while managing plan costs, and implementing processes that are intended to reduce spending for services that are not covered or are not medically necessary. Cost management addresses the need to keep premiums affordable while also managing overall risk to a health plan. The **evidentiary standards and sources** upon which this factor is based are:
    - Stakeholder pressure to control costs of benefits.

- **The nature of the OON service**, meaning whether the service is voluntary or involuntary, is a **factor** used to design the non-participating provider reimbursement strategy. The **evidentiary standards and sources** for this factor are:
    - Based upon the certificate of coverage, involuntary OON claims refer to those claims defined in the certificate of coverage that are provided at a network facility by an out-of-network provider, not available from a network provider, or an emergency service.
    - Voluntary OON claims refer to services members choose to receive from a non-participating provider, if OON coverage is available under the terms of the plan.
    - State law, as applicable.
    - The Federal No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of non-participating provider reimbursement for (a) involuntary OON claims; and (b) voluntary OON claims. Aetna compensates non-participating providers based on the terms of the member's plan, at the lesser of the billed charges or the payable amount based on the payment hierarchies discussed herein. For involuntary M/S and MH/SUD OON claims, the reimbursement amount is based on the factors and rate hierarchy listed below in section (a). For voluntary M/S and MH/SUD OON claims, the allowable amount is determined by the factors and rate hierarchy listed below in section (b). Each step in the respective hierarchies is further explained below. If one step is unsuccessful in producing a rate, the claim continues to the next step in the hierarchy until it is successfully priced. For both voluntary and involuntary OON claims, the rate hierarchies are the same for M/S and MH/SUD benefits.

(a) Factors for establishing the reimbursement amount for involuntary OON claims

The factors for establishing the reimbursement amount for involuntary OON claims are considered in the order presented below. If one factor is unsuccessful in producing a rate, the claim continues to the next step until it is successfully priced. Once a rate is produced, no further factors are considered. Standardly, for both MH/SUD and M/S involuntary claims, regardless of which factor produces a rate for the claim, there is balance billing protection for the member.

Factor	Applicable to M/S	Applicable to MH/SUD
Single case contracts	✓	✓
National Advantage Program (NAP) rates	✓	✓
State and federal law	✓	✓
Facility charge review	✓	✓
Ad hoc negotiations	✓	✓
Non-par reasonable rate[1]	✓	✓
Default rate	✓	✓

1. **Single case contracts** are negotiated when Aetna precertifies a service from a non-participating provider to be covered at the preferred (in-network) benefit level, for both M/S and MH/SUD services. Aetna will attempt negotiations with the provider at the time of precertification (prior to the claim being incurred) to agree on a rate before services are provided. The **evidentiary standards and sources** for this factor are:
    - Aetna negotiates single case contracts when single case contract referral criteria are met. As implemented through Aetna Network policy AETPENO-071699, Aetna will attempt negotiations when the following referral criteria all apply: the out-of-network service has been precertified at the in-network level of coverage; the billed amount is $750 or greater; and Aetna is the primary insurance.

2. **National Advantage Program (NAP) rates** are contracted rates for providers who do not participate in-network with Aetna, but who do have contracted rates for OON services with Aetna through Aetna's NAP vendors. NAP rates apply to both M/S and MH/SUD benefits. The NAP network consists of MH/SUD and M/S facilities, ancillary providers, and physicians contracted through vendor arrangements. The **evidentiary standards and sources** for this factor are:
    - Payment rates established by Aetna's NAP vendors. Vendor arrangements are currently in place with First Health Group Corp. and Claritev.

3. **State and federal law** prescribe how plans must reimburse non-participating providers for emergency services and/or when the member did not voluntarily use out-of-network benefits, for both M/S and MH/SUD services. For claims that are governed by federal surprise billing

[1] Applicable to managed care plans only.

law protections and/or applicable state law, the rate is determined pursuant to this factor and no further factors are applied. The **evidentiary standards and sources** for this factor are:

- The Federal No Surprises Act qualifying payment amount.
- Applicable state-required payment methodology.

4. **Facility charge review** is a factor used to price involuntary OON M/S and MH/SUD facility claims that do not qualify as surprise bill claims. The **evidentiary standard and source** for this factor are:
    - Facility-specific cost-to-charge ratios produced by CMS.
    - For facilities that don't report costs or cost-to-charge ratios to CMS, the facility charge review rate is based on a statewide average of these facilities.

5. **Ad hoc negotiations** are post-service negotiations, which are attempted for individual claims that do not qualify as surprise bill claims and meet the required referral criteria, for both M/S and MH/SUD services. The **evidentiary standards and sources** for this factor are:
    - For both M/S and MH/SUD claims meeting referral criteria, when the eligible charges exceed $1,000 for a facility claim or $4,000 for a professional claim, and no prior step in the hierarchy resulted in a price, ad hoc negotiations will be attempted to achieve a negotiated rate.

6. **Non-par reasonable rate** is used for M/S and MH/SUD claims when the prior steps do not result in a price for the service code. The **evidentiary standards and sources** for this factor are:
    - The non-par reasonable rate is based on a percent of Medicare or Medicare equivalency pricing at the claim line level. For M/S and MH/SUD professional charges, this is typically 125% of Medicare, and for M/S and MH/SUD facility charges, this is 200% of Medicare.
    - In addition to the Medicare rates, the non-par reasonable rate includes non-Medicare rates for codes Medicare does not value, which means this rate will capture claims that were not priced by the plan rate factor.

7. **Default rate** is used for M/S and MH/SUD services when no prior step results in a price for the service code. The **evidentiary standard and source** for this factor is:
    - Standardly, the default rate is 50% of billed charges.

(b) Factors for establishing the allowable amount for voluntary OON claims

The plan's certificate of coverage outlines the method for determining the allowable amount. The generic certificate of coverage in Step 1 includes bracketed ranges within which plans may set the plan rate, which is typically a percentage of Medicare rate or a specified percentile of

the prevailing charges. The rate hierarchy, including the plan rate the plan selects, always applies equally to M/S and MH/SUD claims; Aetna does not permit plans to select a separate rate hierarchy or plan rate for MH/SUD and M/S claims. The factors for establishing the allowable amount for voluntary OON claims are considered in the order presented below. If one factor is unsuccessful in producing a rate, the claim continues to the next step until it is successfully priced. Once a rate is produced, no further factors are considered.

Factor	Applicable to M/S	Applicable to MH/SUD
National Advantage Program (NAP) rates	✓	✓
Plan rate	✓	✓
Provider type	✓	✓
Ad hoc negotiations	✓	✓
Non-par reasonable rate	✓	✓
Default rate	✓	✓

1. **National Advantage Program (NAP) rates** are contracted rates for providers who do not participate in-network with Aetna, but who do have contracted rates for OON services with Aetna through Aetna's NAP vendors. NAP rates apply to both M/S and MH/SUD benefits. The NAP network consists of M/S and MH/SUD facilities, ancillary providers, and physicians contracted through vendor arrangements. The **evidentiary standard and source** for this factor is:
    - Payment rates established by Aetna's NAP vendors. Vendor arrangements are currently in place with First Health Group Corp. and Claritev.

2. **Plan rate** refers to the plan's standard out-of-network rate, which is generally 105% of Medicare rates for professional providers and 140% of Medicare rates for facility providers, or the 80th percentile of prevailing charges. Although the plan may select the plan percentage rate within specific ranges, the percentage rate for both M/S and MH/SUD must be the same. The **evidentiary standards and sources** for this factor are:
    - When the plan rate is a percentage of Medicare rates, the evidentiary standard and source are the CMS fee schedules for both professional and facility fees.
    - When the plan rate is based upon prevailing charges, the evidentiary standard and source is FAIR Health for professional charges and Facility Charge Review for facility charges.
    - For both Medicare and prevailing charges, the allowable amount is further based on the geographic area of the service location.

3. **Provider type** refers to the provider's licensure type (e.g., MD, DO, LCSW, RN). For both M/S and MH/SUD provider types, reimbursement rates are tiered based on the practitioner's licensure. The **evidentiary standards and sources** for this factor are based upon:
    - Practitioner provider type, as implemented through Aetna Policy N004: Non-Physician Providers Payment Policy.
    - The CMS Medicare Claims Processing Manual, which reduces payment for non-physician practitioners.

4. **Ad hoc negotiations** are post-service negotiations and are attempted for individual claims meeting certain criteria. The **evidentiary standards and sources** for this factor are:
    - For both M/S and MH/SUD claims meeting referral criteria, when the eligible charges exceed $1,000 for a facility claim or $4,000 for a professional claim, and no prior step in the hierarchy resulted in a price, ad hoc negotiations will be attempted to achieve a negotiated rate.

5. **Non-par reasonable rate** is used for M/S and MH/SUD claims when the prior steps do not result in a price for the service code. The **evidentiary standards and sources** for this factor are:
    - The non-par reasonable rate is based on a percentage of Medicare or Medicare equivalency pricing at the claim line level. For professional charges, this is typically 125% of Medicare, and for facilities, this is 200% of Medicare.
    - In addition to the Medicare rates, the non-par reasonable rate includes non-Medicare rates for codes Medicare does not value, which means this rate will capture claims that were not priced by the plan rate factor.

6. **Default rate** is used for M/S and MH/SUD claims when no prior step results in a price for the service code. The **evidentiary standard and source** for this factor is:
    - Standardly, the default rate is 50% of billed charges.

Step 3: Description of How Factors are Used in the Design or Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Cost management** is a factor used in the design of this NQTL and refers to efforts to control expenses associated with providing coverage for healthcare services while maintaining quality and accessibility of care for policyholders.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits. In order to manage costs for both members and plans, a reimbursement amount for services obtained out-of-network is established, the goal of which is to reimburse non-participating providers fairly while managing plan costs. All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. Efforts to manage cost by establishing appropriate reimbursement rates is a basis and rationale underlying Aetna's standards and procedures relating to non-participating provider reimbursement.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standard relied upon when designing this NQTL is the overall stakeholder pressure to control the costs of benefits. Failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness and/or ability to continue offering insurance products. This standard applies equally as a general concept to all M/S and MH/SUD benefits. Appropriate management of non-participating provider reimbursement can help reduce health care costs, which in turn can contribute to lower premiums.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition, as it applies to MH/SUD as compared to M/S benefits.

- **Whether the claim is voluntary or involuntary** is a factor used in the design of this NQTL and establishes reimbursement amounts that comply with applicable state and federal legislation, protects members from surprise bills, and separately prices involuntary and voluntary OON claims.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits. Involuntary OON services are those claims defined in the certificate of coverage that are provided at a network facility by an out-of-network provider, not available from a network provider, or an emergency service. Voluntary OON services occur when a member chooses to seek care from a non-participating provider. Both M/S and MH/SUD benefits can be either voluntary or involuntary. All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement, and whether the service is voluntary or involuntary determines whether the allowable amount applies, as described in the certificate of coverage, or whether surprise billing protections and other reimbursement methodologies apply. Step 3, Part 2, encompasses a separate set of factors for voluntary and involuntary OON claims.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards relied upon when designing this NQTL include the member's certificate of coverage, which differentiates between involuntary and voluntary OON services, and the Federal No Surprises Act and applicable state law, which specify what is considered a surprise bill claim and how those claims must be paid. Along with services that are precertified to be covered at the in-network level, surprise bill claims are involuntary OON claims and follow the reimbursement hierarchy described in Part 2, Subpart (a). All other services that are not surprise bill claims or precertified to be covered at the in-network level are voluntary OON claims and follow the reimbursement hierarchy described below in Part 2, Subpart (b).

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition, as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: The factors of cost management and the nature of the OON service (voluntary or involuntary) apply equally and agnostically to both

M/S and MH/SUD benefits in the general design of non-participating provider reimbursement. They are interrelated because they collectively ensure that the plan appropriately reimburses non-participating providers. The factor of cost management is a factor generally underlying the strategy in establishing a reimbursement amount for non-participating providers. Whether the claim is voluntary or involuntary is a differentiating factor in the consideration of how that reimbursement amount is determined, based on the nature of the claim and whether balance bill or surprise bill protections apply. In the design of this NQTL, there is no specific order or hierarchy of these factors as they are considered equally important for an effective non-participating provider reimbursement process. Similarly, no one factor is weighted more than another in the design of this NQTL.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in the application of non-participating provider reimbursement for: (a) establishing non-participating provider reimbursement for involuntary OON claims and (b) establishing the non-participating provider reimbursement for voluntary OON claims.

(a) Factors for establishing the reimbursement amount for involuntary OON claims

1. **Single case contracts** are negotiated when Aetna precertifies a service from a non-participating provider to be covered at the preferred (in-network) benefit level.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies equally to M/S and MH/SUD benefits delivered out-of-network, and the referral criteria for attempting negotiations with a provider are the same for M/S and MH/SUD. For both M/S and MH/SUD, office visits are not eligible for single case contracts. When Aetna precertifies a service from a non-participating provider to be covered at the in-network benefit level, and if referral criteria are met, Aetna will attempt negotiations with the provider at the time of precertification to agree on a rate before services are provided.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Aetna's Network policy AETPENO-071699 details the process of executing letters of agreement with non-participating providers and provides the criteria for referring services for negotiations. Aetna will attempt negotiations when the following referral criteria all apply: the out-of-network service has been precertified at the in-network level of coverage; the billed amount is $750 or greater; and Aetna is the primary insurance.
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: If the referral criteria are met, for both M/S and MH/SUD benefits, Aetna's Single Case Contracting Unit (SCCU) will attempt to negotiate a single case agreement.

Contract negotiations are necessarily individualized based on each instance of single case contracting. Aetna's SCCU is a team of contract negotiators who initiate negotiations with non-participating providers for individual episodes of care that meet the referral criteria. If Aetna and the non-participating provider were unable to negotiate a single-case agreement, the claim proceeds to the next factor.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

2. **National Advantage Program (NAP) rates** are contracted rates for providers that do not participate with Aetna but do have contracted rates with a NAP vendor.
   (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies equally to M/S and MH/SUD benefits delivered out-of-network. Aetna contracts with vendors for the NAP network that offers access to contracted rates for eligible out-of-network claims. The NAP network consists of M/S and MH/SUD facilities, ancillary providers, and physicians contracted through vendor arrangements. When members use a NAP contracted provider, the reimbursement amount is the NAP contracted rate.
   (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards are the payment rates established by Aetna's NAP vendors, First Health Group Corp. and Claritev.
   (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
   (d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

3. **State and federal law** prescribe how plans must reimburse non-participating providers for emergency services and/or when the member did not voluntarily use out-of-network benefits.
   (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies to M/S and MH/SUD services equally. The services subject to surprise billing protections are listed in the member's certificate of coverage, as noted in Step 1: emergency services from an out-of-network provider, ancillary services initiated from emergency services, non-emergency services provided by an out-of-network provider at an in-network facility, and out-of-network air ambulance services. For involuntary OON services precertified for INN coverage, surprise billing provisions do not generally apply. For all involuntary OON claims, Aetna complies with applicable state law implicating non-participating provider compensation. For claims that are governed by federal

surprise billing law protections and/or applicable state law, the rate is determined pursuant to this factor, and no further factors are applied.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are Federal No Surprises Act requirements and the "qualifying payment amount" ("QPA") and/or state required payment methodology for out-of-network claims. The No Surprises Act prohibits non-participating providers and facilities from sending surprise bills to members and defines how the QPA is calculated. The No Surprises Act requires Aetna to calculate the QPA as the median contracted rate for the same or similar service, increased by the consumer price index percentage provided by the IRS. It also requires the non-participating provider to address any disputes with the insurer, keeping members out of the middle, and includes an independent dispute resolution process using an arbitrator when the non-participating provider and insurer cannot resolve the dispute.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

4. **Facility charge review** is used for involuntary facility claims with a billed amount greater than $1,000 where the prior steps do not result in a price for the claim. This factor is not applicable to surprise bill claims.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies equally to M/S and MH/SUD benefits. This rate is intended to price claims where a rate could not be obtained in a previous level of the hierarchy. This factor is not applicable to claims from professional providers. Additionally, for both M/S and MH/SUD claims, Aetna must be the primary insurance, the claim must be assigned to the provider, and specified provider types are not eligible for facility charge review.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Facility Charge Review applies the reimbursement amount to eligible OON facility claims using cost report information facilities submit to CMS, which produces facility-specific cost-to-charge ratios. The reimbursement amount is calculated at 150% of the facility-specific cost-to-charge ratio. Where there is no facility-specific cost-to-charge ratio, Aetna uses the state average facility cost-to-charge ratio, and the reimbursement amount is 140% of the state average cost-to-charge ratio.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

5. Ad hoc negotiations are post-service negotiations and are attempted for individual claims meeting certain criteria. If the provider agrees to a negotiated amount, this becomes the reimbursement amount for the claim, and a signed agreement is secured for each successfully negotiated claim. This factor is not applicable to surprise bill claims.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies to M/S and MH/SUD provider services equally. The same referral criteria apply to both M/S and MH/SUD claims.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Claims are eligible for ad hoc negotiation when no prior step in the hierarchy resulted in a price for the claim, and the eligible charges are billed over $1,000 for facility claims or $4,000 for professional claims. Additionally, Aetna must be the primary insurance, the claim must be assigned to the provider, and specified provider types are not eligible for negotiations.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: Contract negotiations are necessarily individualized based on each instance of ad hoc contracting. Contract negotiators will initiate negotiations with non-participating providers for individual episodes of care that meet the referral criteria. If Aetna and the non-participating provider are unable to negotiate an ad hoc rate, the claim proceeds to the next factor.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

6. Non-par reasonable rate is used when the prior steps do not result in a price for the service code. This factor is not applicable to surprise bill claims.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement, and this factor applies to M/S and MH/SUD services equally. This rate is intended to price claims where a rate could not be obtained from a previous level of the hierarchy. The methodology for determining the non-par reasonable rate is the same for M/S and MH/SUD claims.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The non-par reasonable rate is based on a percentage of Medicare or Medicare equivalency pricing at the claim line level. For M/S and MH/SUD professional charges, this is typically 125% of the Medicare rate for the service, and for M/S and MH/SUD facilities, this is 200% of the Medicare rate. In addition to the Medicare rates, the non-par reasonable rate includes Optum GAP (vendor) and Developed Aetna Rate Table (DART) rates for codes Medicare does not value, which means this rate will capture claims that were not priced by the plan rate factor. There are some services Medicare does not value through the RBRVS payment methodology, referred to as gap codes. Optum 360 values many of these gap codes in the Essential RBRVS GAP Methodology. When no RBRVS rate exists for a service code, Aetna uses the Optum rate as the rate. For codes where there is no CMS or Optum rate, Aetna uses the DART rate. DART rates are based on Aetna's internal claims and national contract defaults.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

7. **Default rate** is used when no prior step results in a price for the service code. This factor is not applicable to surprise bill claims.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement, and this factor applies to M/S and MH/SUD services equally. The default rate is the same percentage of billed charges for both M/S and MH/SUD claims.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The standard default rate is 50% of billed charges. This evidentiary standard ensures that the claim can be priced since it requires no external sources and is based on the amount submitted on the bill.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: These factors are considered in the order presented when processing individual claims. The factor ultimately used to determine the

reimbursement amount for an individual claim is the one that results in a price, at which point no further factors are considered. This hierarchy accounts for involuntary OON claims where Aetna precertifies a service to be covered at the INN level through the factors of single case contracting, followed by the NAP contracted rate if applicable. The next steps in the hierarchy are state law, if applicable, followed by facility charge review for facilities, ad hoc negotiations, the non-par reasonable rate, and default rate. For surprise bill claims, only the factors of NAP rate and state and federal law apply. If a claim is not priced using a NAP rate, Aetna will use the reimbursement methodology specified in the applicable state or federal law.

(b) Factors for establishing the allowable amount for voluntary OON claims

1. **National Advantage Program (NAP) rates** are contracted rates for providers that do not participate with Aetna but do have contracted rates with a NAP vendor.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement, and this factor applies equally to M/S and MH/SUD benefits delivered out-of-network. The NAP network offers access to contracted rates for eligible out-of-network claims. The NAP network consists of M/S and MH/SUD facilities, ancillary providers, and physicians contracted through vendor arrangements. When members use a NAP contracted provider, the allowable amount is the NAP contracted rate.
    (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: These rates are established by Aetna's vendors; vendor arrangements are currently in place with First Health Group Corp. and Claritev.
    (c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.
    (d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

2. **Plan rate** refers to the plan's standard out-of-network rate, which is generally 105% of Medicare rates for professional providers and 140% of Medicare rates for facility providers, or the 80th percentile of prevailing charges. Although the plan may select the plan rate within specific ranges, the rate for both M/S and MH/SUD must always be the same within each plan.
    (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies to M/S and MH/SUD OON services equally.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standard that applies is based on the plan's selected rate. When the plan rate is a percentage of Medicare rates, the evidentiary standard and source are the CMS fee schedules for both professional and facility charges. When the plan rate is prevailing charges, the evidentiary standard is FAIR Health for professional charges and Facility Charge Review for facility charges. For both Medicare and prevailing charges, the allowable amount is based on the geographic area of the service location. Geographic area is normally based using the first three digits of a zip code. If there is insufficient data for a particular service or supply, Aetna may base rates on a wider geographic area, such as the entire state.

When the plan rate is a percentage of Medicare rates, the evidentiary standard is the rates CMS establishes for services and supplies provided to Medicare enrollees without taking into account adjustments for specific provider performance. CMS rates are set quarterly and at the market level; Aetna updates the new rates within 180 days and uses the rate in effect at the service location on the date of service.

The prevailing charge rate is the plan's selected percentile value reported in a database prepared by FAIR Health, a non-profit company. FAIR Health may change these periodically. Aetna updates the new rate within 180 days of receiving them from FAIR Health. If the database becomes unavailable, Aetna may substitute a different, comparable database. If the alternate data source doesn't contain a value for a service or supply, Aetna will base the allowable amount on the Medicare allowed rate.

Facility Charge Review applies the allowable amount to eligible OON facility claims using cost report information facilities submit to CMS, which produces facility-specific cost-to-charge ratios. The allowable amount is calculated at 150% of the facility-specific cost-to-charge ratio. Where there is no facility-specific cost-to-charge ratio, Aetna uses the state average facility cost-to-charge ratio, and the allowable amount is 140% of the state average cost-to-charge ratio.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

3. Provider type refers to the professional provider's licensure and level of education.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. When the allowable amount is based on the plan rate, the factor of provider type applies to M/S and MH/SUD professional services equally. This factor does not apply when the allowable amount is determined by another

factor. For both M/S and MH/SUD, listed provider types are reimbursed at a percentage of the plan rate for physicians based on licensure. This factor is not applicable to facility services.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The CMS Medicare Claims Processing Manual, Chapter 12 – Physicians/Nonphysician Practitioners[2] includes reimbursement at a percentage of the physician rate for physician assistant, nurse practitioner, clinical social worker, marriage and family therapist, and mental health counselor services. Aetna's payment policy N004: Non-Physician Providers Payment Policy documents the provider types and reimbursement percentages used in establishing the allowable amount, in which practitioners are reimbursed at a percentage of the physician rate, based on their education and licensure:

Aetna Reimburses Providers at the Following Percentage of the Allowable Amount for Covered Services:		
	M/S Provider Types	**MH/SUD Provider Types**
100%	• Doctors	• Doctors (Psychiatrist or Addictionologist with MD or DO) • Clinical Psychologists
85%	• Certified Nurse Midwives • Clinical Nurse Specialists (e.g., Nurse Practitioner or Registered Nurse) • Physician Assistants	• Behavioral Health Nurse Practitioners • Behavioral Health Physician Assistants • Psychiatric Nurses
75%	• Audiologists • Genetic Counselors • Massage Therapists • Nutritionists • Registered Dieticians • Respiratory Therapists	• Certified Addiction Counselors • Clinical Social Workers • Drug and Alcohol Counselors • Licensed Professional Counselors • Marriage and Family Counselors • Pastoral Counselors • Psychoanalysts • Psychological Examiners

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

[2] The CMS Medicare Claims Processing Manual Chapter 12 is available online at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

4. **Ad hoc negotiations** are post-service negotiations and are attempted for individual claims meeting certain criteria. If the provider agrees to a negotiated amount, this becomes the allowable amount for the claim and a signed agreement is secured for each successfully negotiated claim.
   (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement, and this factor applies to M/S and MH/SUD provider services equally. The same referral criteria apply to both M/S and MH/SUD claims.
   (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: Claims are eligible for ad hoc negotiation when the prior factors do not return a price and the eligible charges are billed over $1,000 for facility claims or $4,000 for professional claims. Additionally, Aetna must be the primary insurance, the claim must be assigned to the provider, and specified provider types are not eligible for negotiations.
   (c) ***If the factor depends on specific decisions made in the administration of benefits***: Contract negotiations are necessarily individualized based on each instance of ad hoc contracting. Contract negotiators will initiate negotiations with non-participating providers for individual episodes of care that meet the referral criteria. If Aetna and the non-participating provider are unable to negotiate an ad hoc rate, the claim proceeds to the next factor.
   (d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

5. **Non-par reasonable rate** is used when the prior steps do not result in a price for the service code.
   (a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement. This factor applies to M/S and MH/SUD professional provider services equally. This rate is intended to price claims where a rate could not be obtained in a previous level of the hierarchy.
   (b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The non-par reasonable rate is based on a percentage of Medicare or Medicare equivalency pricing at the claim line level. For M/S and MH/SUD professional charges, this is typically 125% of the Medicare rate, and for M/S and MH/SUD facilities, this is 200% of the Medicare rate. In addition to the Medicare

rates, the non-par reasonable rate includes Optum GAP (vendor) and Developed Aetna Rate Table (DART) rates for codes Medicare does not value, which means this rate will capture claims that were not priced by the plan rate factor. There are some services Medicare does not value through the RBRVS payment methodology, referred to as gap codes. Optum 360 values many of these gap codes in the Essential RBRVS GAP Methodology. When no RBRVS rate exists for a service code, Aetna uses the Optum rate as the index rate. For codes where there is no CMS or Optum rate, Aetna uses the DART rate. DART rates are based on Aetna's internal claims and national contract defaults.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

6. Default rate is used when no prior step results in a price for the service code.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: All M/S and MH/SUD benefits delivered out-of-network are subject to non-participating provider reimbursement, and this factor applies to M/S and MH/SUD services equally, as the default rate is the same percentage of billed charges for both M/S and MH/SUD claims.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The standard default rate is 50% of billed charges. This evidentiary standard ensures that the claim can be priced since it requires no external sources and is based on the amount submitted on the bill.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: These factors are considered in the order presented when processing individual claims. The factor ultimately used to determine the allowable amount for an individual claim is the one that results in a price, at which point no further factors are considered. The first factor is whether the non-participating provider has an applicable NAP contracted rate. If so, that reimbursement rate applies, and no further factors are considered. The next factors, plan rate and provider type, are considered together, because the reductions for practitioners based on licensure are only applied when the allowable amount is based on the plan rate. If the plan rate does not result in a reimbursement amount for the claim, the remaining factors

are considered. Ad hoc claim negotiations are attempted for high dollar claims that were not priced by the plan rate. The final two factors are only used when no prior factor results in a rate for a claim. The non-par reasonable rate is generally a percentage of Medicare rates but also includes additional rates using non-Medicare rates for certain services not valued by Medicare. Finally, the default rate is used only when no prior factor has resulted in a price for the claim. The default rate is based on a percentage of billed charges, standardly 50%, and therefore will always result in a reimbursement rate.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, ***as written****, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts:* ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, non-participating provider reimbursement applies to all M/S and MH/SUD benefits delivered by an OON provider, including the following benefit classifications: out-of-network inpatient; out-of-network outpatient; both office and all other; and emergency services. As noted in Step 2, Part 1, the factors used in designing non-participating provider reimbursement, cost management and the nature of the OON service (voluntary or involuntary), are general design factors that apply equally and comparably, as written, to M/S and MH/SUD services.

Cost management, as defined in Step 2, Part 1 above, is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD benefits. Cost management as a design factor is further articulated in CVS Health public filings, which

acknowledge that failure of an insurer or health plan administrator to manage benefit costs could lead to a deterioration of market competitiveness. This is reflected in the CVS Health Form 10-K for the fiscal year ending December 31, 2025 (see, e.g., Form 10-K at page 34: "Our Health Care Benefits segment's operating results and competitiveness depend in large part on our ability to appropriately manage future health care and other benefit costs through . . . medical management programs."). While this material refers to the general design factor of promotion of cost management, there is no written documentation that more specifically explains how the factor of cost management wase used in the design of non-participating provider reimbursement with respect to M/S and MH/SUD benefits.

The nature of the OON service is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD benefits. Whether the service is voluntary or involuntary determines the hierarchy that is applied to determine the non-participating provider reimbursement amount. Whether a service is voluntary or involuntary is differentiated in the member's certificate of coverage, as described in Step 1. A voluntary OON claim is for services a member chooses to obtain from a non-participating provider where the plan has OON benefits and is paid based upon the allowable amount. An involuntary OON claim is for services or supplies that are not available from a network provider, provided at a network facility by an out-of-network provider, or emergency services. The certificate of coverage further describes services provided at a network facility by an out-of-network provider and emergency services for purposes of describing surprise billing protections. The certificate of coverage defines surprise billing, lists what qualifies as a surprise bill claim, explains how the QPA is calculated, and instructs members what to do upon receiving a surprise bill. These provisions of the certificate of coverage apply equally to both M/S and MH/SUD benefits.

The factors of cost management and the voluntary/involuntary nature of the service are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the design of non-participating provider reimbursement. As written, the processes, strategies, evidentiary standards or other factors used in designing non-participating provider reimbursement with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing the NQTL with respect to M/S benefits in the applicable benefits classifications.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 2, Part 2, the factors for non-participating provider reimbursement are different for: (a) establishing the reimbursement amount for involuntary OON claims; and (b) establishing the allowable amount for voluntary OON claims. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying non-

participating provider reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying non-participating provider reimbursement to M/S benefits.

The below internal written policies are predicated upon the member's certificate of coverage. These policies reflect the above-referenced factors, evidentiary standards, and sources for each step in the non-participating provider reimbursement hierarchy. As stated throughout this analysis, where applicable. Aetna follows and applies federal and/or state requirements regarding non-participating provider reimbursement and/or surprise billing protections. Overall, Aetna applies its internal Nonparticipating Provider Compensation (Pricing) Policy to both involuntary and voluntary OON M/S and MH/SUD claims. The Nonparticipating Provider Compensation Policy defines the reimbursement amount and details each step of the hierarchy in determining the same, including technical instructions for claim processing staff to check the plan provisions for plan-specific elections and state legislation, which are used in the application of this NQTL when claims are priced.

(a) Establishing the reimbursement amount for involuntary OON claims

As noted in Step 2, Part 2, the factors used in application, to establish reimbursement for a non-participating provider involuntary claim, are: 1) single case contracting; 2) NAP rates; 3) state and federal law; 4) facility charge review; 5) ad hoc negotiations; 6) non-par reasonable rate; and 7) default rate. In addition to the member's certificate of coverage, Aetna applies the following internal policies in calculating non-participating provider reimbursement for involuntary OON claims:

- Nonparticipating Provider Compensation (Pricing) Policy
- NCS 512: Non-Participating Provider Requests for In-Network Benefits P&P
- AETPENO-071699: Single Case Letters of Agreement

As referenced above, an involuntary OON claim may arise where there is a claim: 1) for services that are not available from a network provider or 2) where services are provided at a network facility by an out-of-network provider or an emergency service which implicate state and federal surprise billing law. In either instance, **Aetna's Nonparticipating Provider Compensation (Pricing) Policy**, which applies equally to M/S and MH/SUD services, defines the reimbursement amount and details each step of the hierarchy in determining the same. Because non-participating provider reimbursement is established for individual claims at the time of processing, this policy includes detailed instructions for claim processing staff to verify plan provisions, federal and state requirements, and internal system definitions.

For claims authorized as INN (where services were not available from a network provider), this policy details the hierarchy, which aligns to the factors discussed in the prior steps, for M/S and MH/SUD facilities, and separately for M/S and MH/SUD professional providers. Specifically,

the policy provides instructions to determine whether a rate can be derived based upon the following, in order:

1. Single case contracted rate
2. NAP rate
3. State and federal law
4. Facility Charge Review or ad hoc negotiations
5. Non-par reasonable rate
6. Default rate

In addition to federal law, the policy also includes information on states with separate requirements, ensuring proper application of state law. Standardly, for both M/S and MH/SUD involuntary claims, regardless of which factor produces a rate for the claim, there is balance billing protection for the member.

Additionally, for involuntary OON claims for services that are not available from a network provider, **NCS 512: Non-Participating Provider Requests for In-Network Benefits P&P** outlines handling non-participating provider coverage requests during the precertification process including referrals for single case contracting. This policy applies equally to M/S and MH/SUD benefits as to the process and criteria for authorization, and relevant to reimbursement, includes the procedure and required criteria for referral of approved OON services to Aetna's Single Case Contracting Unit (SCCU), which will attempt to negotiate the fees. Standardly, for Aetna's insured plans, M/S and MH/SUD office visits are not eligible for single case contracting. For MH/SUD, all services other than office visits are eligible for single case contracting if the referral criteria are otherwise met. However, there are additional limitations on the types of M/S services that are eligible. Aside from the type of service, services are eligible for single case contracting when the following criteria are met, which apply equally to M/S and MH/SUD services:

- Services are approved at the preferred (in-network) benefit level
- Services are rendered by non-participating providers
- Aetna is the primary insurance carrier
- The service is estimated to cost more than $750

Single case contracting procedure is further established, in an equal manner for both M/S and MH/SUD services, pursuant to **Aetna Policy AETPENO-071699: Single Case Letters of Agreement**. This policy defines the process for single case contracting, a/k/a executing a Letter of Agreement. As noted in the policy's scope, this applies equally to M/S and MH/SUD providers. The pre-service single case contract process includes steps for how approved OON services are referred to the SCCU and includes requirements for the letter of agreement documentation, all of which apply equally to M/S and MH/SUD services and providers.

Additionally, for services that were provided at a network facility by an out-of-network provider or an emergency service, which implicate state and federal surprise billing laws, the **Nonparticipating Provider Compensation (Pricing) Policy** further provides instructions for paying such claims in accordance with applicable law. For both M/S and MH/SUD, the QPA is

based on the median contracted rate for the same or similar services, adjusted annually by a rate the IRS determines.

(b) Establishing the allowable amount for voluntary OON claims

As noted in Step 2, Part 2, the factors used in application, to establish reimbursement for a voluntary OON claim, are: 1) NAP rates; 2) plan rate; 3) provider type; 4) ad hoc negotiations; 5) non-par reasonable rate; and 6) default rate. In addition to the member's certificate of coverage, Aetna applies the following internal policies in calculating non-participating provider reimbursement for voluntary OON claims:

- Nonparticipating Provider Compensation (Pricing) Policy
- N004: Non-Physician Providers Payment Policy
- AETPENO-071143 Non Par National Default Fee Schedule P&P

As referenced above, the **Nonparticipating Provider Compensation (Pricing) Policy** applies equally to M/S and MH/SUD services, defines the allowable amount, and details each step of the allowable amount hierarchy, which align to the factors listed in this comparative analysis. Specifically, the policy provides instructions to determine whether a rate can be derived based upon the following, in order:

1. NAP rate
2. Plan rate (generally a percentage of Medicare rates or a percentile of FAIR Health and Facility Charge Review)
3. Ad hoc negotiations
4. Non-par reasonable rate
5. Default rate

As noted above, because non-participating provider reimbursement is established for individual claims at the time of processing, this policy includes detailed instructions for claim processing staff to verify plan provisions, state requirements, and internal system definitions.

In addition to the instructions set forth in the Nonparticipating Provider Compensation (Pricing) Policy, **N004: Non-Physician Providers Payment Policy** addresses the reimbursement rate for specific non-physician provider types when the plan rate is used to price the claim. A non-physician provider is defined as a healthcare professional who is not a Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO). Non-physicians are also known as non-physician practitioners or non-physician health providers. This payment policy lists which provider types are reimbursed at a percentage of the physician's allowable amount for the service. As shown below, for both M/S and MH/SUD, clinical nurse specialists and physician assistants are reimbursed at 85% of the physician's rate. For both M/S and MH/SUD, other masters-level provider types are reimbursed at 75% of the physician's rate.

Aetna Reimburses Providers at the Following Percentage of the Allowable Amount for Covered Services:		
	M/S Provider Types	**MH/SUD Provider Types**
100%	• Doctors	• Doctors (Psychiatrist or Addictionologist with MD or DO) • Clinical Psychologists
85%	• Certified Nurse Midwives • Clinical Nurse Specialists (e.g., Nurse Practitioner or Registered Nurse) • Physician Assistants	• Behavioral Health Nurse Practitioners • Behavioral Health Physician Assistants • Psychiatric Nurses
75%	• Audiologists • Genetic Counselors • Massage Therapists • Nutritionists • Registered Dieticians • Respiratory Therapists	• Certified Addiction Counselors • Clinical Social Workers • Drug and Alcohol Counselors • Licensed Professional Counselors • Marriage and Family Counselors • Pastoral Counselors • Psychoanalysts • Psychological Examiners

In addition to the instructions set forth in the Nonparticipating Provider Compensation (Pricing) Policy, where a claim is not priced based on NAP rate, plan rate, facility charge review or ad hoc negotiation, Aetna's policy **AETPENO-071143 Non Par National Default Fee Schedule P&P** documents the policy and procedure for the non-par reasonable rate factor for managed products, which applies to both M/S and MH/SUD services. The policy requires the rates within this fee schedule to be consistently priced at 125% of the Medicare rate, using geographic localities for all codes with RVUs published within RBRVS, which includes both M/S and MH/SUD professional services. The non-par reasonable rate includes prices for service codes Medicare does not price, and these are obtained from Optum 360 (vendor), Developed Aetna Rate Table (DART), and national initiatives, all of which apply equally to M/S and MH/SUD services. Specific to M/S services, this policy also includes pricing sources for other M/S codes that are not included in RBRVS: durable medical equipment, laboratory, enteral and parenteral services, ambulance, drugs, immunizations, and anesthesia. The policy requires that the fee schedule will be updated annually, that new codes will be updated quarterly as they are released, and that Aetna's MEU is responsible for maintaining this fee schedule.

In sum, the factors listed above for determining reimbursement for both voluntary and involuntary OON claims are equally applicable to MH/SUD and M/S benefits, and are not applied, as written, incomparably or more stringently to MH/SUD benefits. Together with the certificate of coverage for the specific plan, the policies and procedures discussed in this Step 4 represent the written material used in the application of non-participating provider reimbursement. These

policies are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. As written, the processes, strategies, evidentiary standards and other factors used in applying non-participating provider reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying the NQTL to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL, in operation, and the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the MH/SUD and M/S benefits to which the NQTL is applicable.

As noted in Step 1, non-participating provider reimbursement applies to all M/S and MH/SUD benefits delivered by an OON provider, including the following benefit classifications: out-of-network inpatient; out-of-network outpatient, both office and all other; and emergency services. As noted in Step 2, Part 2, different factors are considered or relied upon to determine non-participating provider reimbursement for (a) involuntary OON claims and (b) voluntary OON claims. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying non-participating provider reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying non-participating provider reimbursement to M/S benefits across the applicable benefit classifications.

Non-participating provider reimbursement is calculated for each claim at the time of processing based on the factors described in this comparative analysis. There is no standard or set rate for overall non-participating provider reimbursement. In operation, for M/S and MH/SUD services, Aetna applies the same rate hierarchies discussed above to determine the reimbursement amount for involuntary and voluntary OON claims.

To further evaluate non-participating provider reimbursement in operation, Aetna reviews reimbursement amounts for M/S and MH/SUD physicians compared to the Medicare rate for the same service code. The chart below reflects reimbursement rate data for claims paid in 2026 for Virginia's insured book of business for non-participating M/S and MH/SUD office-based

providers, the corresponding Medicare relativity, and the total number of units billed. The Medicare relativity is based on the Medicare rate for the particular claim, thereby taking into consideration the date of service and geographic location. This chart shows the four most frequently billed shared codes, meaning these codes may be billed by both M/S and MH/SUD providers, as a way to compare reimbursement rates for M/S and MH/SUD physicians for the same code.

06/30/25-07/01/26 Average Physician[3] Reimbursement by Service Code				
Provider Type	**Service Code[4]**	**Average Reimbursement**	**Average Medicare Relativity**	**Units Billed**
MH/SUD Physician	99203	$0	0%	0
MH/SUD Physician	99204	$174	100%	3
MH/SUD Physician	99213	$129	139%	53
MH/SUD Physician	99214	$173	132%	232
M/S Physician	99203	$124	101%	60
M/S Physician	99204	$183	103%	22
M/S Physician	99213	$122	128%	114
M/S Physician	99214	$156	115%	132

This in operation data shows that for both M/S and MH/SUD physicians, the most frequently billed shared codes are 99213 and 99214. When considering these two most frequently billed shared codes, both the average dollar amount paid and Medicare relativity are higher for MH/SUD physicians than for M/S physicians. For 99213, both the average reimbursement amount and average Medicare relativity were higher for MH/SUD physicians, at $129 (139% of Medicare) compared to $122 (128% of Medicare) for the M/S physician. Similarly, for 99214, the MH/SUD

[3] The physician provider types for MH/SUD are psychiatrists and addictionologists, and the M/S physicians are M/S primary care and specialists.

[4] 99203: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.

99204: Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.

99213: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.

99214: Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.

physician average reimbursement was $173 (132% of Medicare) compared to the $156 (115% of Medicare) for the M/S physician. The remaining two codes, 99203 and 99204, were billed significantly fewer by MH/SUD physicians, and there was no reimbursement for MH/SUD physicians for code 99203. These differences are not statistically significant and should not be interpreted as evidence of deficiency. Numerous factors may influence a member's decision not to seek care from an out-of-network provider. For example, members may select and prefer in-network providers based on geographic convenience, provider availability, affordability considerations, continuity of care, personal preference or other situations not known.

Accordingly, the differences do not demonstrate non-compliance; rather the data should be evaluated within the broader context of the provider availability and other relevant operational and market factors.

Taken together and in the aggregate, the analysis conducted demonstrates that in operation, the processes, strategies, evidentiary standards, and other factors used in designing and applying non-participating provider reimbursement for MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying non-participating provider reimbursement for M/S benefits in the applicable benefit classifications. As such, Aetna's analysis of the "in operation" review used to assess non-participating provider reimbursement shows that those factors and the related evidentiary standards are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services than to M/S services.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR 146.137(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, non-participating provider reimbursement is payment to out-of-network providers for covered services provided to members. Non-participating provider reimbursement applies to all M/S and MH/SUD benefits delivered out-of-network, including the following benefit classifications: out-of-network inpatient; out-of-network outpatient, both office and all other; and emergency services. Step 2 identified factors considered or relied upon in the design of non-participating reimbursement and to establish the reimbursement rates for both involuntary and voluntary OON claims. Step 3 explained the evidentiary standards and sources for those factors. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD claims and concluded that there are no written differences in that application that results in any MH/SUD benefits being treated more stringently than, or incomparably to, M/S benefits. Finally, Step 5 demonstrated that, in operation, MH/SUD and M/S non-participating provider reimbursement rates are determined in a comparable manner.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors, evidentiary standards, and sources, in designing and applying non-participating provider reimbursement to M/S and MH/SUD providers. The factors of cost management and the nature of the OON service (voluntary or involuntary) apply equally and agnostically to both M/S and MH/SUD benefits in the general design of non-participating provider reimbursement. Cost management is a factor generally underlying the strategy in establishing a reimbursement amount for non-participating providers, which attempts to

appropriately control costs while compensating non-participating providers fairly for covered services. Additionally, the design factor of whether the OON services were voluntary or involuntary, which accounts for surprise billing protections and services precertified to be covered as in-network, applies equally to M/S and MH/SUD services, and determines which payment hierarchy as discussed herein applies to determine the reimbursement amount. In application, for both involuntary and voluntary OON claims, the payment hierarchy applies equally to M/S and MH/SUD services. While plans have flexibility within specified ranges to select the plan rate, which is used to price voluntary OON claims, the plan rate must always be consistent for both M/S and MH/SUD services. Plans are not permitted to select disparate plan rates for M/S and MH/SUD services. Furthermore, within each step of the payment hierarchies, the underlying evidentiary standards and sources for each pricing methodology apply comparably to M/S and MH/SUD claims.

As demonstrated in Steps 4 and 5, both in writing and in operation, Aetna applies the same policies, procedures, and rate hierarchies discussed above to determine the reimbursement amount for involuntary and voluntary OON claims. There are no differences, either in writing or in operation, in how the factors, evidentiary standards, and sources are applied that result in MH/SUD benefits being treated incomparably or in a more stringent manner than M/S benefits. Additionally, an in-operation review of non-participating provider reimbursement shows that MH/SUD reimbursement rates are generally higher than or close to M/S reimbursement rates as compared to Medicare rates for the most frequently billed shared codes. Specifically, Aetna reviewed reimbursement rate data for claims paid in 2025-26 for non-participating M/S and MH/SUD office-based physicians. Of the four most frequently billed shared codes (codes that can be billed by both M/S and MH/SUD providers), the average reimbursement amount and Medicare relativity was higher for MH/SUD physicians than M/S physicians for two of the four evaluated codes. For the one shared code which reflected lower average reimbursement and Medicare relativity for MH/SUD providers, this code was only billed 3 times by MH/SUD providers over the course of the year. The remaining code was not billed by MH/SUD providers during the reporting timeframe. Using an external benchmark of Medicare rates, this in-operation data demonstrates that non-participating provider reimbursement is applied comparably and not more stringently to MH/SUD providers.

From this information, Aetna concludes that, both in writing and in operation, across all applicable benefit classifications, the processes, strategies, evidentiary standards, and other factors used to design and apply non-participating provider reimbursement to MH/SUD benefits are comparable to, and are not applied more stringently than, the processes, strategies, evidentiary standards and other factors used to design and apply non-participating provider reimbursement to M/S benefits. Taken together, the factors, sources, and evidentiary standards, as well as the written materials and in-operation review, demonstrate that the non-participating professional provider reimbursement NQTL is applied comparably and no more stringently to MH/SUD benefits than M/S benefits.

CONTAINS CONFIDENTIAL INFORMATION AND TRADE SECRETS OF AETNA. THIS INFORMATION IS EXEMPT FROM STATE OR FEDERAL FREEDOM OF INFORMATION ACT REQUESTS AND SHALL NOT BE REDISCLOSED PURSUANT TO CONTRACTUAL LIMITATIONS.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Executive Director, Medical Economics Unit • Executive Director, National Network Management

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Nonquantitative Treatment Limitation Comparative Analysis:
PROVIDER CREDENTIALING

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of credentialing, and* ***(2)*** *an identification of all medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits to which credentialing applies, and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Credentialing [45 CFR 146.137(c)(1)(i)]

Credentialing is a process by which a health care organization reviews and evaluates the qualifications of licensed professionals and facilities. This includes, but is not limited to, relevant training, licensure, certification and/or registration to practice in a health care field, and academic background. Credentialing is done before a health care provider joins Aetna's network and is a separate process from network contracting. All practitioners and organizational providers participating in Aetna's networks, both M/S and MH/SUD, must satisfy the credentialing or assessment criteria discussed herein for admission to participate in the network or for continued network participation. Aetna's credentialing elements or requirements do not vary by any fee-for-service arrangements or value-based model as these payment models govern how the provider is reimbursed after participation. Additionally, for delegated provider groups and entities, the delegated organization is responsible for credentialing providers according to Aetna's credentialing standards and requirements. We own Minute Clinic and the providers who work there are our employees. Minute Clinic offers both M/S and MH/SUD services. Minute Clinic has a delegated credentialing arrangement and therefore follows the delegation responsibilities as noted above.

Please Refer to Appendix J for list of credentialed and non-credentialed provider types. Appendix B outlines the criteria for facility and provider participation (and is broken out by provider types).

Virginia Regulations: We comply with the requirements of Code of Virginia § 38.2-3407.10:1. which requires that a carrier that credentials the physicians in its network must establish reasonable protocols and procedures for reimbursing new provider applicants, after being credentialed by the carrier, for health care services provided to covered persons when the applicant's credentialing application was pending. At a minimum, the protocols and procedures must:

- Apply only if the physician's credentialing application is approved by the carrier
- Permit physician reimbursement for services rendered from the date the physician's completed credentialing application is received by the carrier
- Apply only if a contractual relationship exists between the carrier and the physician or entity for whom the physician is employed or engaged and
- Require that any reimbursement be paid at the in-network rate that the physician would have received had he been, at the time the covered health care services were provided, a credentialed participating physician in the network for the applicable health benefit plan.

In response to this law, Aetna implements a method to find and rework any claims processed using non-par R&C. These are claims that fall in between the credentialing date and the contract effective date. We rework them using the provider's new contract rate. Non-participating providers (and therefore not credentialed) will be subject to the plan's allowed amount which is based on R & C or a percentage of Medicare.

Further, Section 38.2-3407.10:1 requires:

- B.1: If the carrier accepts applications through an online credentialing system, the carrier shall notify a new provider applicant through the online credentialing system that the provider has submitted and attested to the application as notice by the carrier that the application is received. If the carrier does not accept applications through an online credentialing system, the carrier shall within 10 days of receiving an application provide notification to the new provider applicant either by mail or electronic mail, as selected by the applicant, that the application was received.
- B.2: Beginning January 1, 2024, a new provider applicant's application is deemed complete within 30 days of the carrier receiving the application, unless the carrier has provided notice that the application is not complete. Notice shall be provided by electronic mail unless the provider applicant has selected notification by mail;
- B.3: The carrier shall approve or deny new provider applicant credentialing applications within 60 days of receiving a completed application;

We comply with the requirements of law VCA § 38.2-3407.6 **Exclusion of podiatrist not permitted under certain circumstances** which requires**:**

> No podiatrist shall be excluded from participating in any preferred provider plan pursuant to this chapter or Chapter 42 (§ 38.2-4200 et seq.) of this title or health maintenance organization pursuant to Chapter 43 (§ 38.2-4300 et seq.) of this title (or HMO) solely because such preferred provider plan or health maintenance organization HMO requires that participating health care providers have active medical staff privileges or admitting medical staff privileges at specified hospitals, provided that the podiatrist has a delineation of privileges that enables such podiatrist to perform the type of services that are covered by the preferred provider plan or health maintenance organization at the designated

hospital or hospitals. The Commission shall have no jurisdiction to adjudicate controversies arising out of this section.

In response to this law, Aetna will not Aetna will not deny a podiatrist participation in the network based on lack of admitting privileges in a participating hospital.

The following materials describe credentialing:

1. Plan Documents

The member's certificate of coverage describes in-network providers, all of which have satisfied the credentialing and assessment criteria discussed herein. Virginia's standard certificate of coverage provides:

Certificate of Coverage – VA AL HCOC 14

Who provides the care

Network providers

We have contracted with **providers** to provide **covered services** to you. These **providers** make up the network for your plan.

2. Provider Contracts

Aetna's template provider contract for non-facility health care professionals sets forth the obligations of Aetna's participating providers with respect to credentialing. Specifically, under "General Obligations", the template contract states, "Provider agrees that it and all Group Providers will: comply with Company's credentialing/recredentialing requirements...; Provider understands that no Group Provider may serve as a Participating Provider until that provider is fully credentialed and approved by the applicable peer review committee." The same template provider contract is used for both M/S and MH/SUD providers.

3. Facility Contracts

Aetna's template provider contract for facility providers states: "General obligations. Facility agrees that it and all Facility Providers will: ... (b) obtain and maintain all applicable license(s), certification(s), registration(s), authorization(s) and accreditation(s) required by Applicable Law and conduct all credentialing, privileging, and re-appointment in accordance with Applicable Law and its medical staff by-laws, regulations, and policies; . (d) comply with Company's credentialing/recredentialing requirements and applicable Participation Criteria; Facility understands that no Facility Provider may serve as a Participating Provider until that provider is fully credentialed and approved by the applicable peer review committee; . (i) maintain an ongoing internal quality assurance/assessment program that includes, but is not limited to, the credentialing, supervision, monitoring and oversight of its employees and contractors providing services under this Agreement." The same template provider contract is used for both M/S and MH/SUD providers.

4. Provider Manual

Credentialing requirements are summarized in Aetna's Provider Manual, applicable to participating providers. Additionally, credentialing criteria by provider type are included in Aetna's Provider and Facility Participation Criteria. Specifically, the sections: "Applicability," "Insurance," and "Professional competence and conduct" detail the requirements to remain in the network as a credentialed provider. Please see Appendix B for the Provider Manual and Provider and Facility Participation Criteria provisions applicable to credentialing.

5. Policies and Procedures

Aetna's Quality Management (QM) Program Description, which applies to M/S and MH/SUD benefits, outlines credentialing as a component of the QM Program and also details the accountability and committee structure for QM activities. The QM Program Description provides the foundation for QM policies and procedures (P&Ps). The following internal QM policies and procedures, which apply to both M/S and MH/SUD benefits, address credentialing:

- **QM 01: Quality Management and Credentialing Policy and Procedure Development and Review P&P** establishes consistent QM and credentialing policies, procedures, and state-specific amendments across Aetna. This policy states that QM policies will be developed with input from the departments involved in implementation and oversight of the policies, and that policies must be approved by the Quality Management Policy Committee and adopted by the National Quality Oversight Committee (NQOC).
- **QM 54: Practitioner Credentialing/Recredentialing Policy** specifies when practitioners must be credentialed, designates contractual requirements that are primarily verified and designates the data elements and sources for primary verification, describes authority for making decisions regarding compliance with specified criteria, and establishes requirements for ongoing monitoring of sanctions and member complaints and appeals against practitioners.
- **Virginia Amendment to QM 54**: This amendment is written to meet regulatory and legislative requirements specified in Title 12 of the Virginia Administrative Code that impact the QM 54, Practitioner Credentialing/Recredentialing policy pursuant to health plans licensed in the state of Virginia. This amendment will be used in conjunction with QM 54 to comply with Virginia requirements.
- **QM 53: Credentialing Allied Health Practitioners** specifies when allied health professionals must be credentialed, designates contractual requirements that are primarily verified, describes authority for making decisions regarding compliance with specified criteria, and establishes requirements for ongoing monitoring of sanctions and member complaints and appeals against allied health professionals. Allied health practitioners are healthcare practitioners, other than physicians, dentists, chiropractors, or podiatrists, who are prepared through an appropriately accredited higher educational institution or appropriate training program, who are duly licensed, registered or certified by national or state regulatory bodies and whose practice is regulated by state or federal law.
- **Virginia Amendment to QM 53:** This amendment is written to meet regulatory and statutory requirements under Virginia law that impact the QM 53, Credentialing Allied Health

Practitioners policy for fully insured health plans in Virginia. This amendment will be used in conjunction with QM 53 to comply with Virginia requirements.

- **QM 56: Practitioner Application Policy** addresses privacy and security of provider application data, primary source verification and required data elements, and the provider notification process.
- **QM 62: Practitioner Participation and Peer Review Policy** establishes the policy requirements and standards for formal peer review of individually licensed health care practitioners applying to or participating in Aetna networks, defines the circumstances and process under which a practitioner may appeal certain professional review actions which adversely affect a practitioner's network participation, and defines practitioner appeal committee rules.
- **QM 51: Assessment of Organizational Providers** specifies facilities and ancillary providers that must be assessed by Aetna prior to finalizing the network contract. This policy also defines the criteria and method for assessing each type of facility or ancillary provider unless otherwise specified in state specific amendments.
- **QM 59: Delegated Credentialing/Recredentialing** establishes a consistent process and procedure for the assessment and oversight of potential and contracted credentialing delegates seeking authority or continued authority to credential participating practitioners and organizational providers. Aetna may delegate credentialing functions to entities that are participating providers in the Aetna network and that demonstrate compliance with federal, state, accreditation, and Aetna credentialing standards and processes.

The below internal Network and Provider Data Services policies and procedures, which apply to both M/S and MH/SUD benefits, address credentialing and assessment:

- **AETNPS-065188: Credentialing Policy Management Process** defines policy development and annual review of credentialing-related QM policies.
- **AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process:** M/S and MH/SUD facility and ancillary provider types that do not require credentialing per NCQA, URAC, or state and federal requirements are subject to this P&P. These providers are required to satisfy an equivalent network assessment, which utilizes the same evaluation criteria used to credential organizational providers, prior to admission to Aetna's provider network. This P&P specifies the facility and ancillary providers that must be assessed by Aetna prior to finalizing network contracting, defines the criteria and method for assessing each type of provider, and defines Network Management's process and procedure for obtaining and verifying provider documentation prior to contracting.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Overview

Credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits delivered in-network. This NQTL applies to all in-network providers, including practitioners and organizational providers, and by extension applies to all benefits delivered by in-network

providers. All M/S and MH/SUD in-network practitioners are credentialed prior to admission to Aetna's provider network. An organizational provider is a facility or ancillary provider that provides services to members and where members are directed for services rather than to a specific practitioner. M/S and MH/SUD organizational providers, depending on facility type, must either be credentialed or satisfy an equivalent network assessment, both of which utilize identical evaluation criteria, prior to admission to Aetna's provider network.

Benefits and Classification

Credentialing or an equivalent assessment applies to M/S and MH/SUD benefits in the following benefit classifications: **in-network inpatient**; **in-network outpatient**, both **office** and **all other** subclassifications; and **emergency**.

Benefit Classifications to which NQTL Applies: ✓ INN IP ✓ INN OV ✓ INN OP AO ✓ Emergency	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
Applies to all M/S benefits delivered in-network	Applies to all MH/SUD benefits delivered in-network

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of credentialing. Each subpart includes:* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to credentialing, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards) " that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL - Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL, for both practitioners and organizational providers.

Factor	Applicable to M/S	Applicable to MH/SUD
Quality care and service to members	✓	✓
Operation of the NQOC and related groups	✓	✓

- **Quality care and service to members** is a **factor** and **strategy** providing a basis for Aetna's provider credentialing and assessment processes. Aetna designs the credentialing, recredentialing, and assessment processes to promote quality care and service to members. Aetna's Quality Management Program Description outlines credentialing as a component of the QM Program and also details the accountability and committee structure for QM activities. The **evidentiary standards** and **sources** for this factor are:
  - NCQA Standards and Guidelines for the Accreditation of Health Plans and NCQA Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Credentialing and Recredentialing ("NCQA CR" and "NCQA MBHO CR") and URAC Credentials Verification Organization accreditation standards.
  - In some states, an additional evidentiary standard and source for this factor is state credentialing standards. Where applicable, state-defined standards may require certain types of providers to be credentialed or may include requirements for other aspects of the credentialing program.

• **Operation of the NQOC and related groups** is another basis for Aetna's **strategy** in credentialing providers. The National Quality Oversight Committee (NQOC) is a multidisciplinary committee composed of representatives from Aetna departments, which adopts the QM policies that govern provider credentialing, among other duties. Aetna's Network and Provider Data Services department is involved in implementation and oversight of these policies, in conjunction with Aetna's National Quality Management Policy Team, which serves as a review body for all credentialing policies. The **evidentiary standards** and **sources** for this factor are:

- NCQA Standards and Guidelines for the Accreditation of Health Plans, Quality Management and Improvement ("NCQA QI") and NCQA Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Quality Management and Improvement ("NCQA MBHO QI"), which provide requirements and guidance for a plan's quality improvement committee's composition and responsibilities.

Step 2, Part 2. Application of the NQTL - Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for: (a) the procedure for performing credentialing and recredentialing; (b) credentialing practitioners; and (c) credentialing and assessing organizational providers.

(a) The procedure for performing credentialing and recredentialing

The procedure for performing credentialing and recredentialing is a **factor** and **process** used in the application of credentialing. The procedures described herein for credentialing and recredentialing are applicable to both M/S and MH/SUD providers.

Factor	Applicable to M/S	Applicable to MH/SUD
Procedure for performing credentialing and recredentialing	✓	✓

• **Credentialing** must be performed prior to contracting with providers. M/S and MH/SUD practitioners complete a credentialing application in the Council for Affordable Quality Healthcare (CAQH) Provider Data Portal or use a state-developed application as required by state legislation. **Recredentialing** is conducted every three years for continued participation in the Aetna network for credentialed M/S and MH/SUD providers. Aetna follows a documented process for reviewing M/S and MH/SUD credentialing and recredentialing applications, through which Aetna staff verify each of the factors listed below in (b) for M/S and MH/SUD practitioners, and in (c) for M/S and MH/SUD organizational providers. The **evidentiary standards and sources** for this factor are:

- NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification, which require Aetna

to follow a documented process for reviewing credentialing applications and verifying each of the factors listed in (b) and (c). Aetna implements these NCQA standards and guidelines through the policies and procedures discussed herein.

(b) Factors considered in credentialing practitioners

As a prerequisite for participation in an Aetna provider network, all M/S and MH/SUD practitioners must meet all the factors listed below:

Factor	Applicable to M/S	Applicable to MH/SUD
Provider qualifications	✓	✓
Sanction and exclusion information	✓	✓
History of professional competence and conduct	✓	✓

- **Provider qualifications** means that Aetna conducts timely verification of information to verify that practitioners have the legal authority to provide care and have relevant training and experience. The **evidentiary standards and sources** for this factor are:
  - NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification, Element A: Verification of Credentials, which requires Aetna to verify the following: 1) a current and valid license to practice; 2) a valid DEA or CDS certificate, if applicable; 3) education and training; 4) board certification status, if applicable; and 5) work history. This is implemented through Aetna's QM 53: Credentialing Allied Health Practitioners and QM 54: Practitioner Credentialing/Recredentialing Policy.
  - The practitioner's complete application with the data elements required by the NCQA guidelines and implemented by Aetna's QM 56: Practitioner Application Policy.

- **Sanction and exclusion information** is whether the practitioner has received any state sanctions, restrictions on licensure and limitations on scope of practice, or Medicare and Medicaid sanctions and exclusions. The **evidentiary standards and sources** for this factor are:
  - NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification, Element B: Sanction and Exclusion Information and is implemented through Aetna's QM 54: Practitioner Credentialing/Recredentialing Policy. Practitioners currently on a sanction list are not eligible to join the network. Providers with closed actions require further investigation through the peer review committee.
  - The Office of Inspector General (OIG) Sanction Lists and *The Government-wide List of Parties Excluded* from *Federal Procurement and Non-procurement Programs*, the CMS Preclusion List, and state board sanction lists.

- **History of professional competence and conduct** means the practitioner attests to

additional elements supporting their ability to provide care. The **evidentiary standards** and **sources** for this factor are:

- NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification, Element C: Credentialing Application, which requires Aetna to verify that the provider attests to the following: 1) reasons for inability to perform the essential functions of the position; 2) lack of present illegal drug use; 3) history of loss of license and felony convictions; 4) history of loss or limitation of privileges or disciplinary actions; 5) current malpractice insurance coverage; and, 6) current and signed attestation confirming the correctness and completeness of the application. This is implemented through Aetna's QM 53: Credentialing Allied Health Practitioners and QM 54: Practitioner Credentialing/Recredentialing Policy.
- The practitioner's self-reported confidential information form, curriculum vitae or work history, the National Provider Database (NPDB), and state licensing boards.

(c) Factors considered for credentialing and assessing organizational providers

All organizational providers participating in Aetna's networks, both M/S and MH/SUD, must satisfy the same credentialing or assessment criteria listed below.

Factor	Applicable to M/S	Applicable to MH/SUD
State and federal regulatory requirements	✓	✓
Business assessment	✓	✓
Accreditation	✓	✓

- **State and federal regulatory requirements** means the organizational provider is in good standing with state and federal agencies, including state licensure, and good standing with Medicare and Medicaid, as appropriate. The **evidentiary standards and sources** for this factor are:
  - NCQA CR 7 and NCQA MBHO CR 7, Assessment of Organizational Providers, Element A: Review and Approval of Provider, which requires Aetna to confirm that the provider is in good standing with state and federal regulatory bodies. This is implemented through Aetna's QM 51: Assessment of Organizational Providers Policy and Procedure for provider types that are credentialed, and Aetna's Network Policy 232: Non-Credentialed Providers Pre-Contracting Process.
  - The state's licensing or accreditation body and the Office of Inspector General (OIG) Sanction Lists and *The Government-wide List of Parties Excluded from Federal Procurement and Non-procurement Programs*, the CMS Preclusion List, and state board sanction lists.

- **Business assessment** means the provider must have current professional liability insurance in adequate amounts. The **evidentiary standards and sources** for this factor are:
    - The minimum amount required by state law, or in the absence of state law requiring a minimum level of coverage, an insurance amount that is customarily maintained by providers in the state or region in which the provider operates. This is implemented through Aetna's QM 51: Assessment of Organizational Providers Policy and Procedure for provider types that are credentialed, and Aetna's Network Policy 232: Non-Credentialed Providers Pre-Contracting Process.

- **Accreditation** means review and approval by an accrediting body in all service locations where services are provided to members. For unaccredited facilities, Aetna will accept a current compliant CMS or state survey in lieu of accreditation. If a current CMS or state survey is unobtainable, Aetna will conduct an onsite quality assessment and ensure the facility has a process for credentialing their providers. The **evidentiary standard** and **sources** for this factor are:
    - NCQA CR 7 and NCQA MBHO CR 7, Assessment of Organizational Providers, Element A: Review and Approval of Provider, which requires Aetna to confirm the provider has been reviewed and approved by an accrediting body and requires Aetna to conduct an onsite quality assessment if the provider is not accredited. This is implemented through Aetna's QM 51: Assessment of Organizational Providers Policy and Procedure for provider types that are credentialed, and Aetna's Network Policy 232: Non-Credentialed Providers Pre-Contracting Process.
    - The accrediting agency's website or database, or a CMS or state survey in lieu of accreditation.

Step 3: Description of How Factors are Used in the Design or Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL - How Factors are Used [45 CFR 146.137(c)(3)]

- **Quality care and service to members** is a factor used in the design of this NQTL as a basis for evaluating providers prior to adding them to the network. Aetna follows a well-defined process for evaluating providers.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing applies to all M/S and MH/SUD benefits delivered by in-network providers. The factor of quality care and service to members applies to all M/S and MH/SUD benefits delivered in-network.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: Aetna plans meet NCQA Health Plan and Managed Behavioral Health accreditation requirements, which include credentialing policy and process standards for evaluating providers to join the Aetna network. Aetna is committed to Health Plan and Managed Behavioral Health Organization accreditation as one means of demonstrating a commitment to continuous quality improvement and meeting customer expectations. The evidentiary standards relied upon when designing this NQTL are the NCQA CR, NCQA MBHO CR, and URAC Credentials Verification Organization (CVO) standards. NCQA and URAC, as accrediting bodies, provide guidance on the qualifications of the credentialing committee designated to make recommendations regarding credentialing decisions, how Aetna verifies credentialing information, and how frequently providers must be recredentialed. To obtain and maintain accreditation, NCQA and URAC survey Aetna's policies, procedures, and outcomes. Credentialing is part of three accreditations Aetna holds: NCQA Health Plan Accreditation, NCQA Managed Behavioral Healthcare Accreditation, and URAC Credentials Verification Organization Accreditation. For organizational provider types that do not require credentialing by a state law or regulation, or

NCQA or URAC guidelines, Aetna requires an equivalent assessment as a prerequisite for the provider joining the network. The types of practitioners and organizational providers Aetna credentials or assesses are listed in Appendix J. These accreditation guidelines and standards are implemented through Aetna's policies listed in Step 1 and further explained in Step 4. These standards apply to both M/S and MH/SUD benefits.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

• **Operation of the NQOC and Related Groups** is a factor used in the design of this NQTL as a basis for Aetna's strategy in credentialing providers:

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing applies to all M/S and MH/SUD benefits delivered by in-network providers. This factor applies to all M/S and MH/SUD benefits delivered in network, as the groups discussed herein develop and approve policies and procedures that pertain to provider credentialing, recredentialing, and assessment processes. Aetna's quality improvement committee is the NQOC, a multidisciplinary committee composed of representatives from Aetna departments: the Office of the Chief Medical Officer, Medical Directors, National Quality Management, Clinical Services, Behavioral Health Quality Management, Pharmacy Management, Network Management, Customer Service, Claims Processing, Complaints Grievances and Appeals, and National Accounts, among others, including Medicare departments and external participants. Adopting the QM policies that govern provider credentialing is one duty of the NQOC and supports the committee's other initiatives, which is why representation is so extensive. Notably, the committee includes representation from Aetna's Behavioral Health business segment for all functions: Medical Directors, Network Management, Clinical Health Services, Customer Service, and Quality Management. The NQOC voting member roster is included in Appendix H. The QM policies and procedures that govern the design of the credentialing NQTL are developed by Aetna's Network and Provider Data Services, which is the department involved in implementation and oversight of these policies, in conjunction with Aetna's National Quality Management Policy Team, which serves as a review body for all credentialing policies.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards and sources relied upon in designing this NQTL are the NCQA QI and NCQA MBHO QI. These guidelines provide requirements for a plan's quality improvement committee's composition and responsibilities. NCQA QI requires, at minimum, one M/S and one MH/SUD physician involved in the committee. Additionally, the MBHO QI guidelines require substantial involvement of a designated behavioral health care practitioner in the QM program and specifies that the committee is responsible for recommending policy decisions, analyzing and evaluating results of quality management activities, ensuring practitioner participation in the quality management program, identifying needed actions, and ensuring follow-

up as needed.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: The two factors referenced herein provide the basis for the design of Aetna's credentialing, recredentialing, and assessment processes. Efforts to promote quality care and service to members, by verifying the qualifications of providers admitted to the network, are a basis and rationale underlying Aetna's standards and procedures relating to credentialing and assessing M/S and MH/SUD providers. The operation of the NQOC and related groups explains the basis and composition of the staff that deliberates on the design of the credentialing and recredentialing standards and procedures. These factors are complementary and weighted the same for both M/S and MH/SUD providers.

Step 3, Part 2. Application of the NQTL - How Factors are Used [45 CFR 146.137(c)(3)]

The following describes how factors are used in the application of credentialing for: (a) the procedure for performing credentialing and recredentialing; (b) credentialing practitioners; and (c) credentialing and assessing organizational providers.

(a) The procedure for performing credentialing and recredentialing

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies to all M/S and MH/SUD benefits delivered in-network. For practitioners and organizational providers who render both M/S and MH/SUD services, as a prerequisite for joining the network, Aetna requires credentialing or an equivalent assessment. A practitioner is an individual who is licensed or otherwise authorized by their state to provide health care services. Aetna credentials practitioners when an independent relationship exists, which means Aetna lists the practitioner by name in the network directory, from which Aetna members select participating providers. An organizational provider is a facility or ancillary provider that provides services to members, and where members are directed for services rather than to a specific practitioner. Organizations can be freestanding or hospital based. For organizational providers, Aetna credentials those provider types where NCQA, URAC, or a state requires credentialing. For other organizational provider types, Aetna network staff conduct an equivalent assessment of the provider's credentials.

For practitioners, Aetna credentialing staff review the data element factors listed below in section (b) and will discontinue review of applications submitted in CAQH that are incomplete or that do not meet all business requirements. Complete applications are forwarded to an Aetna medical director for review. Aetna medical directors or their physician designees have authority to make determinations of practitioner compliance with business requirements. Medical directors are Aetna employees who are actively licensed physicians. Medical directors can approve a file in which the

applying practitioner meets all requirements for credentialing, including license and other qualifications. For practitioner applicants whose files require further investigation, application of the provider qualifications factor depends on specific decisions made by a peer review committee. If the applying practitioner has an encumbered license, including limited or conditions on practice, or if the provider meets criteria listed in QM 54 and QM 53 requiring further investigation, the application will be referred for further investigation. Aetna will collect additional detailed information from the applicant, which will be reviewed by a peer review committee, the Credentialing and Performance Committee (CPC). A CPC is composed of providers participating in the Aetna network, who are not Aetna employees, representing a range of specialties that include primary care and high- volume specialists, behavioral health practitioners including a psychiatrist, a psychologist and a master's level behavioral health clinician. Participating practitioners who practice in an applicant's similar specialty may be appointed to a CPC as an ad hoc voting member for the purpose of reviewing a practitioner's application if the committee composition does not include a participating practitioner in the applicant's general area of specialty. The CPC meets monthly to vote on whether applicants whose files were referred for further investigation meet the provider qualification requirements to be admitted to the network. This peer review committee has the authority for making final determinations for applicants requiring further investigation to ensure they meet Aetna's established requirements.

If a practitioner appeals an adverse credentialing or recredentialing determination, a Practitioner Appeals Committee (PAC) will review the appeal. The PAC shall be composed of a majority of members that are peers of the affected practitioner, including three to seven participating network practitioners, at least one of whom is licensed in the same state as the practitioner being reviewed. Additionally, at least one PAC member shall practice in a specialty substantially similar to the specialty of the practitioner, if knowledge of the specialty is required by the nature of the appeal. The PAC may uphold, overturn, or revise the adverse determination. The decision of the PAC is final unless the practitioner requests a second level appeal. The second level appeal is conducted in the same manner as the first level appeal, with a PAC comprised of practitioners not involved in the first level hearing. The decision of the second level PAC is final.

For organizational providers subject to credentialing by state law or regulation, NCQA or URAC requirements, Aetna credentialing staff will confirm that each organizational provider meets all of the participation requirements listed below in section (c) in all service locations. Organizational providers requiring further investigation are reviewed by the NQOC. Organizational providers are not offered appeal rights at the time of credentialing or recredentialing, unless specified in the provider's contract or state requirements. For organizational providers not subject to credentialing by state law or regulation, NCQA or URAC requirements, Aetna network staff review all documentation to ensure the provider meets the equivalent criteria listed below in section (c).

Recredentialing is conducted every 3 years for practitioners and credentialed organizational providers and is based on review of the same factors set forth below in section (b) and (c).

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the***

NQTL: The evidentiary standard that is relied upon when applying this factor is NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification, which requires Aetna to have a well-defined credentialing and recredentialing process. These NCQA guidelines require Aetna to define its procedure for managing and reviewing applications, the procedure for notifying applications of decisions and appeal rights, the process for securing the confidentiality of information obtained in the credentialing process, and the process for documenting information and activities in credentialing files. Aetna implements these processes through the Aetna QM policies and procedures listed with each factor. Additionally, Aetna's Network policies require an equivalent assessment of organizational provider types for which there is no NCQA, URAC, or state requirement for credentialing. These policies and the procedure for performing credentialing, recredentialing, and assessment are further discussed in detail in Step 4, Part 2.

Aetna's turnaround time goal for practitioner and facility initial credentialing decisions is 40 calendar days, in the absence of a state-specific requirement. Aetna's turnaround time goal for practitioner recredentialing decisions is 90 calendar days and for organizational provider recredentialing decisions, the turnaround time goal is 60 calendar days, in the absence of a state-specific requirement. Written notification of credentialing decisions is sent to the applicant within 10 business days. The evidentiary standard for this factor is NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification. This guideline requires Aetna to follow a documented process for reviewing credentialing applications and verifying each of the factors listed below.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: The procedure for credentialing and recredentialing does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from the procedure of credentialing or recredentialing, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

(b) Factors for credentialing practitioners

As a pre-requisite for participation in an Aetna provider network, all M/S and MH/SUD practitioners must meet all the factors below: provider qualifications, sanction and exclusion, and professional competence and conduct. The below addresses these factors and how they are used in the application of credentialing.

- **Provider qualifications** means that Aetna conducts timely verification of information to verify that practitioners have the legal authority to provide care and relevant training and experience.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing applies to all M/S and MH/SUD benefits provided by in-network practitioners. The factor of provider qualifications applies to all M/S and MH/SUD practitioners. The following qualifications require primary source verification: 1) a valid, current, unencumbered license for the state(s) in which the practitioner will provide care for Aetna members; 2) a valid, current,

unencumbered Drug Enforcement Administration (DEA) or state narcotics registration; 3) education and training, including residency or post-graduate training; and 4) board certification. Primary sources are the organization or entity that originally conferred or issued an element used in credentialing or the data bank(s) to which those organizations report (e.g., state licensing boards, schools or training programs, certifying boards, Diversion Control Division web site, National Practitioner Data Bank (NPDB), Federation of Chiropractic Licensing Boards, professional liability carriers, Office of Inspector General (OIG), Office of Personnel Management (OPM)). The practitioner's work history is not verified by primary source, but Aetna requires a 5-year work history from the application attestation date. Timely verification means that at the time of the credentialing committee decision, the application attestation signature is not older than 180 calendar days, and Aetna must verify the practitioner's license to practice is current and within 120 calendar days of the credentialing decision date.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA CR 3 and MBHO CR 3, Credentialing Verification, Element A: Verification of Credentials, which require Aetna to verify the following: 1) a current and valid license to practice; 2) a valid DEA or Controlled Dangerous Substances (CDS) certificate, if applicable; 3) education and training; 4) board certification status, if applicable; and 5) work history. This is implemented through Aetna's QM 54: Practitioner Credentialing/Recredentialing Policy and QM 53: Credentialing Allied Health Practitioners.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: Aetna does not credential or contract with practitioners without an active license and qualifications. As detailed in QM 62, if a practitioner has an encumbered license, the CPC will review the application. In addition, Aetna may grant exceptions to the DEA certificate requirement in limited circumstances for nurse practitioners, psychiatric nurses, physician assistants, physicians and podiatrists when 1) they are joining a participating provider group and another practitioner can prescribe controlled substances to their patients as needed or 2) the practitioner has indicated that the patients under their care do not require controlled substances. Aetna may also grant exceptions to the board certification requirement when practitioners demonstrate they have completed American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) training and it has been less than five years since completing residency training, or if the provider has completed required continuing medical education. However, neither of these exceptions are a deviation from the factor, as the provider must still demonstrate qualifications. There are no deviations or variations from the factor of provider qualifications, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

• **Sanction and exclusion information** is whether the practitioner has received any state sanctions, restrictions on licensure and limitations on scope of practice, or Medicare and Medicaid

sanctions and exclusions.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing applies to all M/S and MH/SUD benefits provided by in-network practitioners. The factor of sanction and exclusion information applies to all M/S and MH/SUD practitioners. Practitioners may not participate in the network if they are on the Office of Inspector General (OIG) sanctions list or *The Governmentwide List of* Parties *Excluded from Federal Procurement and Non-procurement Programs* (i.e., the Office of Personnel Management (OPM) Debarment list) when identified during primary verification of credentials or by ongoing review of OIG or OPM lists. Practitioners who appear on OIG/OPM lists are immediately terminated and notified. A practitioner may not participate in the network if listed on the CMS Preclusion List when identified during primary verification of credentials, or by ongoing review of Preclusion Lists. A participating practitioner who appears on Preclusion Lists will be immediately terminated and there is no right to appeal.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA CR 3 and NCQA MBHO CR 3, Credentialing Verification, Element B: Sanction and Exclusion Information, and are implemented through Aetna's QM 54: Practitioner Credentialing/Recredentialing Policy and QM 53: Credentialing Allied Health Practitioners. Aetna's credentialing policies require ongoing monitoring of sanctions, including the OIG sanctions list or *The Government-wide List of Parties Excluded from Federal Procurement and Non-procurement Programs* (i.e., the OPM debarment reports), CMS Preclusion Lists, and state board sanctions.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

• **History of professional competence and conduct** means the practitioner attests to additional elements supporting their ability to provide safe and quality care.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing applies to all M/S and MH/SUD benefits provided by in-network practitioners. The factor of professional competence and conduct applies to all M/S and MH/SUD practitioners. Practitioners must attest to 1) their ability to perform the essential functions of the position; 2) lack of present illegal drug use; 3) history of loss of license and felony convictions; 4) history of loss or limitation of privileges or disciplinary actions; 5) current malpractice insurance coverage; and 6) current and signed attestation confirming the correctness and completeness of the application. Practitioners being considered for exceptions to Aetna's established requirements for professional competence and conduct go through peer review to determine whether the applicant meets the professional competence and conduct requirements.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA CR 3 and

NCQA MBHO CR 3, Credentialing Verification, Element C: Credentialing Application, and are implemented through Aetna's QM 54: Practitioner Credentialing/Recredentialing Policy and QM 53: Credentialing Allied Health Practitioners. Aetna's credentialing policies require applicant practitioners to attest to their professional competence and conduct and maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by providers in the state or region. Aetna also verifies disciplinary and malpractice history through primary sources.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits. All practitioners, both M/S and MH/SUD, including those referred to the CPC for peer review, must demonstrate a history of professional competence and conduct.

Relationship, ordering, and weighting of multiple factors: With respect to the application of credentialing for practitioners, all factors are weighted the same for M/S and MH/SUD. Credentialing will be discontinued if the M/S or MH/SUD practitioner applicant does not have a license or demonstrate professional qualifications or has been sanctioned, debarred, or appears on a preclusion list. All M/S and MH/SUD practitioners must meet all the factors of provider qualifications, sanction and exclusion information, and history of professional competence and conduct. Practitioners meeting all these factors are approved for admission to the network.

(c) Factors for credentialing and assessing organizational providers

As a prerequisite for participation in an Aetna provider network, all M/S and MH/SUD organizational providers must meet all the factors below: state and federal regulatory requirements, business assessment, and accreditation. The below addresses these factors and how they are used in the application of credentialing and assessing organizational providers.

• **State and federal regulatory requirements** means the organizational provider is in good standing with state and federal agencies, including state licensure and good standing with Medicare and Medicaid as appropriate.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits provided by in-network organizational providers. This factor applies the same to all

M/S and MH/SUD organizational providers. The organizational provider must have a current unencumbered state license/certification and certificate of occupancy and be in good standing with Medicare and Medicaid.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA CR 7 and NCQA MBHO CR 7, Assessment of Organizational Providers, Element A: Review and Approval

of Provider, and are implemented through Aetna's QM 51: Assessment of Organizational Providers Policy and Procedure, and Network Policy AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process. Aetna's policies require organizational providers, as a prerequisite for participation in Aetna's networks, to satisfy all three of the participation assessment requirements (factors) in all service locations. Specifically, Aetna requires primary source verification of the organizational provider's standing with applicable state and federal agencies, including the applicable state licensing board, OIG/OPM, and CMS preclusion lists. Aetna does not credential or contract with providers that do not have a current unrestricted license, certification, or certificate of occupancy as required by the organization's state. Additionally, Aetna does not credential or contract with organizations appearing on the OIG sanctions list or OPM debarment reports or a CMS Preclusion List.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definitions as it applies to MH/SUD as compared to M/S benefits.

• **Business assessment** means the organizational provider has current professional liability insurance in adequate amounts.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits provided by in-network organizational providers. The factor of business assessment requirements applies to all M/S and MH/SUD organizational providers. The organizational provider must show current professional liability insurance in adequate amounts.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA CR 7 and NCQA MBHO CR 7, Assessment of Organizational Providers, Element A: Review and Approval of Provider and implemented through Aetna's QM 51: Assessment of Organizational Providers Policy and Procedure and Network Policy AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process. Aetna's policies require organizational providers to maintain professional liability and malpractice insurance in adequate amounts. Organizational providers must maintain general and professional liability and other insurance according to state requirements; if there are no state requirements, then the amount should be what is typically maintained in the state or region. Aetna does not credential or contract with providers that do not have current liability insurance.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

• **Accreditation** means review and approval by an accrediting body in all service locations where services are provided to members.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: Credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits provided by in-network organizational providers. The factor of accreditation applies to all M/S and MH/SUD organizational providers. The organizational provider must be currently accredited or certified in all its service locations where services are provided to Aetna members. The accreditation can be from several recognized accrediting agencies, specific to the type of organizational provider.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards relied upon when applying this factor are NCQA CR 7 and NCQA MBHO CR 7, Assessment of Organizational Providers, Element A: Review and Approval of Provider and implemented through Aetna's QM 51: Assessment of Organizational Providers Policy, and Procedure, and Network Policy AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process. Aetna's credentialing and assessment policies require organizational providers to have been reviewed and approved by an accrediting body. If the organization is not accredited, Aetna will accept a current CMS or state survey in lieu of accreditation, and if this is unobtainable, an Aetna on-site quality assessment is required. Aetna does not credential organizational providers that do not demonstrate quality care either through a current accreditation or a current on-site assessment.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits. All organizational providers, both M/S and MH/SUD, must maintain current accreditation or demonstrate quality through a CMS or state survey, or an Aetna on-site assessment.

Relationship, ordering, and weighting of multiple factors: With respect to the application of credentialing and assessment for organizational providers, all factors are weighted the same: state and federal regulatory requirements, business assessment, and accreditation. An organizational provider that does not meet all factors will not be admitted to the network.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

This Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Within each such discussion, this Step 4 addresses* ***(a)*** *documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification,* ***(b)*** *in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL,* ***(c)*** *documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and* ***(d)*** *as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits delivered in network, including the following benefit classifications: in-network inpatient; in-network outpatient, both office and all other; and emergency services when provided by an in-network provider. As noted in Step 2, Part 1, the factors relied upon in the design of Aetna's credentialing standards and procedures are: 1) quality care and service to members and 2) operation of the NQOC and related groups. Efforts to provide quality care and service to members, by verifying the qualifications and professional competence and conduct of providers, are a basis and rationale underlying Aetna's standards and procedures relating to credentialing providers, while the operation of the NQOC and related groups explains the basis and composition of the staff that deliberates and makes decisions on the design of the credentialing standards and processes. These factors are applied the same and comparably, as written, to M/S and MH/SUD benefits.

Aetna's efforts to promote quality care and service to members, as defined in Step 2, Part 1, above, is a general design concept that does not distinguish between, and is applied to, both M/S and MH/SUD benefits. As explained above, credentialing is a component of Aetna's Quality Management Program. Aetna's NQOC reviews and approves the **Quality Management (QM)**

Program Description each year. The QM Program influences more than credentialing, but specific to credentialing and network composition, the QM Program's goal is "to maintain effective, efficient and comprehensive practitioner/provider selection and retention processes through credentialing and recredentialing activities." The QM Program Description outlines the components of the QM program, including credentialing and recredentialing, and also details the accountability and committee structure for QM activities. The QM program operates in compliance with and is responsive to applicable requirements of plan sponsors, federal and state regulators, and appropriate accrediting bodies, including the NCQA. The QM Program Description refers to the evidentiary standards of commitment to NCQA accreditation as one means of demonstrating a commitment to quality, as well as ensuring compliance with applicable state laws, which are applied the same with respect to M/S and MH/SUD services. The QM Program Description provides the foundation for the QM policies discussed in Step 4, Part 2 below.

Additionally, the QM Program Description sets forth documentation relating to the NQOC and related groups that make decisions relating to the design of credentialing standards and procedures. The QM Program Description describes the purpose of the NQOC and its role and responsibilities, which include adoption of quality management policies and procedures, including the QM policies that implement the NCQA and URAC guidelines for credentialing. These policies are developed by Network and Provider Data Services, which is the Aetna department involved in implementing and overseeing the policies related to network adequacy, in conjunction with the Accreditation Governance Team and subject to the approval of the NQOC. As set forth above, the NQOC is a multidisciplinary committee composed of department personnel representing both M/S and MH/SUD expertise across several functional areas. The NQOC includes representation from Aetna's behavioral health business segment for all functions: medical directors, network management, clinical health services, customer service, and quality management. The NQOC voting member roster is included in Appendix H.

Specifically, as part of Aetna's accreditation, NCQA reviews the documented processes, policies, and procedures, and determines the same are sufficient to achieve NCQA accreditation. The internal policy and procedure **QM 01: Quality Management and Credentialing Policy and Procedure Development and Review Policy and Procedure** establishes a consistent process for developing and reviewing QM policies. Similarly, Network policy **AETNPS-065188** defines the policy development and annual review of credentialing-related QM policies. These policies state that QM policies will be developed with input from the departments involved in implementation and oversight of the policies, and that policies must be approved by the QM Policy Committee and adopted by the NQOC. Additionally, policies will be reviewed for necessary revisions at least annually. These policies are applied the same to M/S and MH/SUD services. The factors of quality care and service to members and the operation of the NQOC and related groups are applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the design of credentialing. As written, the processes, strategies, evidentiary standards or other

factors used in designing credentialing with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing credentialing with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits delivered in network, including the following benefit classifications: in-network inpatient; in-network outpatient; both office and all other; and emergency services when provided by an in-network provider. As noted in Step 2, Part 2, different factors are applied in the context of credentialing depending on whether the M/S or MH/SUD provider joining the network is a practitioner or organizational provider. This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying credentialing to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying credentialing to M/S benefits across the applicable benefit classifications.

The below internal written policies reflect the above-referenced evidentiary standards and sources of applicable state law and the NCQA credentialing guidelines. When state laws/regulations vary from the core requirements of QM and Network policies, they are documented in a state amendment. As stated throughout this analysis, where a state has applicable regulations, Aetna follows and applies the most stringent standard as between Aetna core requirements and the state requirements. More stringent state requirements supersede both Network and QM policy requirements.

(a) The procedure for performing credentialing and recredentialing

Aetna applies the same internal policies and procedures for credentialing, assessing, and recredentialing M/S and MH/SUD providers. The below policies and procedures set forth the relevant procedures, which are applicable to both M/S and MH/SUD providers:

- QM 56: Practitioner Application Policy
- QM 54: Practitioner Credentialing/Recredentialing Policy and the Virginia Amendment to QM 54
- QM 53: Credentialing Allied Health Practitioners and the Virginia Amendment to QM 53
- QM 62: Practitioner Participation and Peer Review Policy
- QM 51: Assessment of Organizational Providers
- QM 59: Delegated Credentialing/Recredentialing
- AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process

These policies represent the written strategies and processes Aetna employs to credential, assess, and recredential providers, and are applied the same to both M/S and MH/SUD providers. Each of

these policies is discussed in turn below, demonstrating that they are comparably applied, as written, to M/S and MH/SUD services. Practitioners wishing to participate in Aetna's networks must complete a credentialing application with the information required by Aetna, as further described in Aetna's policy **QM 56: Practitioner Application Policy**. Aetna's credentialing staff primary source verifies the information according to state, federal and accrediting body requirements. The requirements and processes for credentialing M/S and MH/SUD practitioners who are licensed as MD, DO, DPM, DDS or DC (including psychiatrists) are set forth in detail in Aetna's Policy **QM 54: Practitioner Credentialing/Recredentialing Policy**. The requirements and processes for credentialing M/S and MH/SUD allied health professionals (including psychologists, psychiatric nurses, clinical social workers and counselors) are set forth in detail in Aetna's policy **QM 53: Credentialing Allied Health Practitioners**. The procedures for credentialing and assessing organizational providers are set forth in **QM 51: Assessment of Organizational Providers** and Network policy **AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process**. Where Aetna has delegated credentialing to a third party, the delegate is required to use Aetna's criteria or criteria consistent with Aetna's criteria, as further detailed in **QM 59: Delegated Credentialing/Recredentialing**.

Specifically, **QM 56** provides the process by which practitioners apply for credentialing as a prerequisite for joining the network. Both M/S and MH/SUD practitioners standardly apply through the CAQH Provider Data Portal, and Aetna uses the CAQH Provider Data Portal as the standard data source for credentialing and recredentialing. Through CAQH, providers can complete their data profile once and allow multiple payers, including Aetna, to access the application. QM 56 lists the minimum data elements for credentialing and recredentialing, and this list applies to both M/S and MH/SUD practitioners. Similarly, the timeframes and notification processes specified in this policy are applied the same to both M/S and MH/SUD practitioners.

QM 54, which applies the same to MH/SUD and M/S practitioners, specifies when practitioners must be credentialed, designates contractual requirements that are primarily verified, describes authority for making decisions, and establishes requirements for ongoing monitoring of sanctions and member complaints and appeals against practitioners. This policy applies to physicians, podiatrists, chiropractors, and dentists who provide services under medical plans. QM 54 details the types of practitioners that will and will not be credentialed by Aetna. Aetna credentials practitioners when an independent relationship exists, which means Aetna lists the practitioner by name in the network directory, where Aetna members select participating providers. This policy also describes the decision-making authority for compliance with the specified participation criteria. Aetna CVO staff can discontinue applications for practitioners without a valid license or those without complete applications. Medical directors can approve files that meet all requirements. QM 54 also details when applications require further investigation, and these are referred to a peer review committee.

QM 62 establishes the policy requirements and standards for formal peer review of individually licensed health care practitioners applying to or participating in Aetna networks, defines the circumstances and process under which a practitioner may appeal certain professional

review actions which adversely affect a practitioner's network participation, and defines practitioner appeal committee rules. Peer review is conducted for applications requiring further investigation by a CPC, and the CPCs have authority for making final determinations for those M/S and MH/SUD applicants requiring further investigation to ensure they meet Aetna's established requirements for professional competence and conduct. A CPC is composed of representatives from a range of participating practitioners in specialties that include primary care and high-volume specialists, behavioral health practitioners including a psychiatrist, a psychologist and a master's level behavioral health clinician. Participating practitioners who practice in an applicant's similar specialty may be appointed to a CPC as an ad hoc voting member for the purpose of reviewing a practitioner's application if the committee composition does not include a participating practitioner in the applicant's general area of specialty. QM 62 also details which determinations are appealable, the Appeals Committee composition, and the Appeals Committee rules. This policy applies the same to both M/S and MH/SUD practitioners.

QM 53 specifies when allied health practitioners must be credentialed, designates contractual requirements that are primarily verified, describes authority for making decisions, and establishes requirements for ongoing monitoring of sanctions and member complaints and appeals against practitioners. This policy applies to allied health practitioners, which are healthcare practitioners other than physicians, podiatrists, chiropractors, and dentists, who are prepared through an appropriately accredited higher educational institution or appropriate training program, who are duly licensed, registered, or certified by national or state regulatory bodies and whose practice is regulated by state or federal law. For MH/SUD, allied behavioral health practitioners are independent practitioners who are duly licensed or certified to practice independently, including practitioners who may require limited oversight, and recognized under state law. QM 53 details the types of practitioners that will and will not be credentialed by Aetna. Aetna credentials practitioners when an independent relationship exists, which means Aetna lists the practitioner by name in the network directory, where Aetna members can select participating providers. Finally, QM 53 describes the decision-making authority for compliance with the specified participation criteria. Aetna CVO staff can discontinue applications for practitioners without a valid license or those without complete applications. Medical directors can approve "clean files" that meet all requirements. QM 53 also details when M/S and MH/SUD applications require further investigation, and these are referred to a peer review committee, as described above in QM 62. QM 53 applies the same to both M/S and MH/SUD practitioners.

QM 51 and **AETPENO-072002** outline the credentialing and assessment procedures for organizational providers. QM 51, which applies to organizational provider types that require credentialing per state law or regulation, NQCA, or URAC requirements, requires M/S and MH/SUD organizational providers adding or changing service locations to complete an assessment for each new location, and it requires a reassessment every three years (except where law or regulation requires a more frequent reassessment). The timeframes and notification processes specified in this policy apply the same to both M/S and MH/SUD organizational providers. Network policy AETPENO-072002, which applies to organizational providers types that do not

require credentialing per state law or regulation, NCQA, or URAC requirements, requires network management to review the organizational provider's contract application package and confirm all documentation is received and meets criteria for participation prior to proceeding with contracting. If criteria are not met, the prospective provider's documentation will be reviewed by an Aetna Medical Director and/or Network Executive Director for approval or denial. Documentation and reviews will be recorded in Aetna's contracting system. These policies are applied the same with respect to both MH/SUD and M/S providers.

QM 59 establishes a consistent process and procedure for the assessment and oversight of potential and contracted credentialing delegates seeking authority or continued authority to credential participating practitioners. QM 59 is applicable to both practitioners and organizational providers. For both M/S and MH/SUD providers, Aetna may delegate credentialing functions to entities that meet certain requirements and agree to follow Aetna's credentialing requirements. Delegates are participating providers in the Aetna network that demonstrate compliance with federal, state, accreditation, and Aetna credentialing standards and processes. For example, Aetna may consider delegating credentialing functions to entities that conduct peer review, including hospitals, physician hospital organizations, behavioral health organizations, and telemedicine groups. Delegates must have a minimum of 50 providers that fall in the scope of credentialing, must accept delegation of primary source verification and decision making, and the entity must have a credentialing program that has been in place for at least 12 consecutive months. Before delegating credentialing to another entity, Aetna will conduct a pre-assessment audit to evaluate the entity's compliance for meeting NCQA accreditation, federal, state, and Aetna's credentialing standards. Additionally, the credentialing delegate will report credentialing activity to Aetna quarterly or semi-annually unless required more frequently by state regulations. Delegates for M/S and MH/SUD must meet the same qualifications, abide by the same delegation agreement, and follow the same credentialing requirements.

As discussed herein, these policies apply the same to both M/S and MH/SUD. As such, Aetna's analysis of the "as written" materials (Network and QM policies and procedures) used in the procedure of credentialing and recredentialing shows that the factors and the related evidentiary standards are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services.

(b) Credentialing practitioners

As set forth above, the factors for credentialing practitioners are: 1) provider qualifications; 2) sanction and exclusion information; and 3) history of professional competence and conduct, which apply the same to both M/S and MH/SUD practitioners. Aetna applies the following internal policies and procedures for credentialing practitioners:

- QM 54: Practitioner Credentialing/Recredentialing Policy
- QM 62: Practitioner Participation and Peer Review Policy
- QM 53: Credentialing Allied Health Practitioners

These policies, which apply the same to both M/S and MH/SUD practitioners, represent the

written strategies and processes Aetna employs to credential practitioners for admission to the network, and include the three (3) factors and requirements for credentialing practitioners listed above, in addition to procedural components as discussed in section (a). Each of these policies is discussed in turn below, demonstrating that they are comparably applied, as written, to M/S and MH/SUD services.

QM 54: Practitioner Credentialing/Recredentialing Policy specifies when practitioners must be credentialed, designates contractual requirements that are primarily verified, describes authority for making decisions, and establishes requirements for ongoing monitoring of sanctions and member complaints and appeals against practitioners. Pertaining to credentialing practitioners, the attachments within QM 54 detail the specific credentialing requirements, including how they are assessed (for example, primary source verification and required data elements). These requirements reflect the three (3) factors identified in Step 2, Part 2: 1) provider qualifications; 2) sanction and exclusion information; and 3) history of professional competence and conduct. The policy details each of these requirements including the data element and the sources from which it may be verified, specific details that must be assessed, and when further investigation is required. Regarding factor 1) professional qualifications, for both M/S and MH/SUD practitioners, Aetna verifies that the applicant has a valid, unencumbered, license for the state in which the applicant will provide care for Aetna members, and the policy specifies that the license must be verified with the state licensing board. Additional qualifications that are verified via primary sources are the applicant's board certification, education, and medical residency or post-graduate training. Furthermore, for both M/S and MH/SUD practitioners, Aetna secures a five-year work history via the applicant's attestation or curriculum vitae. The policy specifies that the work history should include the years of employment, practice name and address, and position held. Regarding factor 2) sanction and exclusion information, the policy states that Aetna must review the OIG/OPM report for debarment, conviction, restrictions, exclusions, and suspension or revocation, and that the applicant will not be admitted to the network if the M/S or MH/SUD practitioner applicant is listed on the OIG/OPM reports. The policy provides that if the M/S or MH/SUD applicant has any sanction or disbarment that has been removed or closed, the application will proceed through peer review committee, discussed above in (a). Finally, pertaining to factor 3) professional competence and conduct, QM 54 lists the data elements and sources that must be checked. For both M/S and MH/SUD practitioners, these are: disciplinary actions noted in the NPDB and state licensing boards; medical conditions which may impair the applicant's ability to provide care to members as noted in the applicant's confidential information form; and, for recredentialing, Aetna data including member complaints and adverse events. Both M/S and MH/SUD applications requiring further investigation to confirm the applicant meets the criteria for credentialing are referred to the peer review committee, discussed above. These requirements apply the same to both M/S and MH/SUD practitioners**,** and there are no separate requirements for MH/SUD practitioners.

QM 53 specifies when allied health practitioners must be credentialed, designates contractual requirements that are primarily verified, describes authority for making decisions, and establishes requirements for ongoing monitoring of sanctions and member complaints and appeals

against practitioners. The attachments within QM 53 detail the specific credentialing requirements, including how they are assessed (for example, primary source verification and required data elements). These requirements reflect the factors identified in Step 2, Part 2: 1) provider qualifications; 2) sanction and exclusion information; and 3) history of professional competence and conduct. The policy details each of these requirements including the data element and the sources from which it may be verified, specific details that must be assessed, and when further investigation is required. Regarding factor 1) professional qualifications, for both M/S and MH/SUD allied health practitioners, Aetna verifies that the applicant has a valid, unencumbered, license for the state in which the applicant will provide care for Aetna members, and the policy specifies that the license must be verified with the state licensing board. Additional qualifications that are verified via primary sources are the applicant's board certification (if applicable), education, and residency or training program, as applicable. Furthermore, for both M/S and MH/SUD allied health practitioners, Aetna secures a five-year work history via the applicant's attestation or curriculum vitae. The policy specifies that the work history should include the years of employment, practice name and address, and position held. Regarding factor 2) sanction and exclusion information, the policy states that Aetna must review the OIG/OPM report for debarment, conviction, restrictions, exclusions, and suspension or revocation, and that the applicant will not be admitted to the network if the M/S or MH/SUD allied health practitioner applicant is listed on the OIG/OPM reports. The policy provides that if the M/S or MH/SUD applicant has any sanction or disbarment that has been removed or closed, the application will proceed through peer review committee, discussed above in QM 62. Finally, pertaining to factor 3) professional competence and conduct, QM 53 lists the data elements and sources that must be checked. For both M/S and MH/SUD practitioners, these are: disciplinary actions noted in the NPDB and state licensing boards; medical conditions which may impair the applicant's ability to provide care to members as noted in the applicant's confidential information form; and, for recredentialing, Aetna data including member complaints and adverse events. Both M/S and MH/SUD applications requiring further investigation to confirm the applicant meets the criteria for credentialing are referred to the peer review committee, as described above in (a). These requirements apply the same to both M/S and MH/SUD allied health practitioners, and there are no separate requirements for MH/SUD allied health practitioners.

As discussed herein, these policies apply the same to both M/S and MH/SUD practitioners, and there are no separate requirements applicable to MH/SUD practitioners. Aetna's analysis of the "as written" materials (QM policies and procedures) used to credential practitioners shows that the factors and the related evidentiary standards are applied comparably to providers who render M/S and MH/SUD services and are not more stringently applied to providers who render MH/SUD services.

(c) Credentialing and assessing organizational providers

As set forth above, the factors for credentialing and assessing organizational providers

are: 1) state and federal regulatory requirements; 2) business assessment; and 3) accreditation. Aetna applies the following internal policies and procedures for credentialing and assessing organizational providers:

- QM 51: Assessment of Organizational Providers
- AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process

These policies represent the written strategies and processes Aetna employs to credential and assess organizational providers for admission to the network and reflect the three (3) factors and requirements used in credentialing and assessing organizational providers, in addition to reflecting procedural requirements as set forth in section (a).

As set forth above, organizational providers must either be credentialed or subjected to an equivalent assessment prior to being admitted to the provider network. M/S and MH/SUD organizational provider types are subject to credentialing based on NCQA, URAC, or state requirements as further described in Aetna's Policy **QM 51: Assessment of Organizational Providers**. Aetna's credentialing staff primary source verifies the information according to state, federal and accrediting body requirements. For M/S and MH/SUD organizational provider types subject to an equivalent assessment, **AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process**, sets forth the equivalent assessment criteria. Whether the organizational provider is required to be credentialed or subject to assessment, the criteria for approval are the same and reflect the three (3) factors and requirements listed above, as listed pursuant to QM 51 and AETPENO-072002. Each of these policies is discussed in turn below, demonstrating that they are comparably applied, as written, to M/S and MH/SUD services.

QM 51 specifies organizational providers that must be credentialed by Aetna prior to finalizing a network contract and defines the criteria and method for assessing each type of organizational provider. QM 51 lists the minimum data elements for credentialing and recredentialing, and this list applies to both M/S and MH/SUD organizational providers. **AETPENO-072002: Non-Credentialed Providers Pre-Contracting Process** specifies the organizational providers that are not credentialed pursuant to QM 51, but which are assessed by Aetna prior to finalizing network contracting, defines the criteria and method for assessing each type of organizational provider, and defines the process and procedure for obtaining and verifying provider documentation prior to contracting. In either instance, the organizational provider is required to satisfy the factors of 1) state and federal regulatory requirements, 2) business assessment, and 3) accreditation as identified in Steps 2 and 3. For 1) state and federal regulatory requirements, for both M/S and MH/SUD organizational providers, QM 51 and AETPENO-072002 require the organizational provider to be in good standing with state and federal agencies, including state licensure and good standing with Medicare and Medicaid as appropriate. The organizational provider's standing with state and federal agencies is verified through primary sources, including the state licensing board and OIG, OPM, and CMS preclusion lists. Pertaining to factor 2) business assessment, these policies require both M/S and MH/SUD organizational providers to maintain professional liability insurance based on state-required minimum amounts. Finally, for factor 3) accreditation, these policies require both M/S and MH/SUD organizational

providers to be reviewed and approved by an appropriate accrediting body, and these policies specify the relevant accrediting or certifying body for different types of organizational providers (e.g., American Association of Ambulatory Surgery Facilities, Healthcare Facilities Accreditation Program, Commission on Accreditation of Rehabilitation Facilities).

As discussed herein, these policies apply the same to both M/S and MH/SUD organizational providers, and there are no separate requirements for MH/SUD organizational providers. Aetna's analysis of the "as written" materials (QM and Network policies and procedures) used to assess organizational providers shows that the factors and the related evidentiary standards are applied comparably to providers who render M/S and MH/SUD services and are not more stringently applied to providers who render MH/SUD services.

Summary

Credentialing or an equivalent assessment applies to all in-network providers and as such to all in-network benefits for both M/S and MH/SUD. The factors for Aetna's procedure, factors for credentialing practitioners, and factors for credentialing and assessing organizational providers apply comparably to M/S and MH/SUD providers. There are no differences in how the factors are applied to MH/SUD benefits compared to M/S benefits, as written, that result in MH/SUD benefits being treated incomparably or more stringently. As written, the processes, strategies, evidentiary standards and other factors used in applying credentialing to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying credentialing to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

As noted in Step 1, credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits delivered in network, including the following benefit classifications: in-network inpatient; in-network outpatient, both office and all other; and emergency services when provided by an in-network provider. This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying credentialing to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying credentialing to M/S benefits.

Aetna monitors the acceptance and denial rates for credentialing applications processed by Aetna and application processing turnaround time for M/S and MH/SUD providers as measures that can assist in the evaluation of whether credentialing is applied comparably, and not more stringently, to MH/SUD benefits compared to M/S benefits. Evaluation of this data for M/S and MH/SUD providers can provide a basis to evaluate whether, in operation, the factors, evidentiary standards, and sources for credentialing are applied comparably and no more stringently to MH/SUD benefits than they are to M/S benefits. The tables below reflect data for applications Aetna processed in calendar year 2025, showing the number of accepted and denied applications and application processing turnaround time for M/S and MH/SUD providers.

- This data is for Virginia providers and is the same for all products and networks. Credentialing is conducted without regard to network or product, so there is no separation of HMO or PPO credentialing counts.
- Initial credentialing data shows new providers applying for admission to the Aetna network, for which there is an NCQA, URAC, or state requirement for credentialing.
- There are additional providers in Aetna's network where a delegate is responsible for ensuring credentialing standards are met, as well as those organizational provider types subject to an equivalent assessment.
- Recredentialing data reflects the three-year review.
- The Total Applications row reflects the count of complete applications for providers credentialed by Aetna in 2025.
- The M/S column includes medical/surgical providers as well as providers who offer both M/S and MH/SUD services.

- Accepted applications met all the requirements listed in Step 2, Part 2, and were approved by a medical director or CPC.
- Denied applications are those that were referred to a CPC for further investigation and denied based on not meeting the requirements for professional competence and conduct or unencumbered license.
- The average turnaround time is expressed as the number of calendar days from Aetna's receipt of a complete application to the determination date, either medical director approval or CPC determination. In the absence of applicable state law, Aetna's CVO initial practitioner credentialing turnaround time goal is 40 calendar days and for practitioner recredentialing is 90 calendar days, applicable to both M/S and MH/SUD. For organizational providers, the goal is 40 days for initial credentialing and 60 days for recredentialing for both M/S and MH/SUD facilities.

  - Credentialing's standard process meets the state's 60 calendar day credentialing approval or denial decision timeframe requirement established by the Virginia Administrative Code section 38.2-3407.10:1.
  -

2025 Practitioner Initial Credentialing - VA		
	M/S	**MH/SUD**
Total Applications	3574	1895
Accepted	3574	1894
Denied	0	1
% Accepted	100%	99.95%
Turnaround time (days)	9.5	9.4

2025 Practitioner Recredentialing - VA		
	M/S	**MH/SUD**
Total Applications	5787	1956
Accepted	5787	1956
Denied	0	0
% Accepted	100%	100%
Turnaround time (days)	23.2	25.7

2025 Organizational Provider Initial Credentialing - VA		
	M/S	**MH/SUD**
Total Applications	22	16
Accepted	22	16
Denied	0	0
% Accepted	100%	100%
Turnaround time (days)	4.7	3.4

2025 Organizational Provider Recredentialing - VA		
	M/S	**MH/SUD**
Total Applications	108	18
Accepted	108	18
Denied	0	0
% Accepted	100%	100%
Turnaround time (days)	9.2	14.3

Summary

This evaluation of provider credentialing and recredentialing demonstrates that, in operation, across all applicable benefits classifications, the processes, strategies, evidentiary standards and other factors used in designing and applying credentialing with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in designing and applying credentialing with respect to M/S benefits. The framework and process for performing credentialing and recredentialing activities, in operation, is conducted in a comparable manner for MH/SUD and M/S.

The approval rate for Virginia M/S and MH/SUD practitioners applying for initial credentialing is comparable, as 100% for M/S practitioner applications and 99.95% MH/SUD practitioner applications were approved. The average turnaround time for initial credentialing is similar; MH/SUD practitioner average turnaround time was .1 days faster than M/S, and both were lower than Aetna's goal of 40 calendar days. For organizational providers, all M/S and MH/SUD providers applying for initial credentialing were accepted. The average turnaround times for M/S and MH/SUD providers were comparable at 9.2 days for M/S and 14.3 days for MH/SUD, both of which is lower than the goal turnaround time of 40 calendar days. There is no difference in how M/S and MH/SUD applications are processed, and the same team handles applications for both types of providers.

The approval rate for both M/S and MH/SUD practitioners applying for recredentialing was comparable, with both having 100% of providers accepted. For organizational providers, the approval rate was also comparable, as 100% of both M/S and MH/SUD recredentialing applications were accepted. The average turnaround time for practitioner and organizational provider recredentialing application processing was also comparable, though there were slight differences between MH/SUD and M/S providers. For practitioner recredentialing, average processing time was 2.5 days faster for M/S providers than MH/SUD; however, the average processing time for both M/S (23.2 days) and MH/SUD providers (25.7 days), were well within the established goal of 90 calendar days. For organizational provider recredentialing, average processing time was 5.1 days faster for M/S providers (9.2 days) than MH/SUD (14.3 days). However, again, the average processing time for both M/S and MH/SUD providers was well within the established goal of 60 calendar days. These differences in average recredentialing processing time are not significant and are not suggestive of a difference in comparability.

Furthermore, practitioners and organizational providers remain in-network during the recredentialing process, and therefore there is no disruption to member access to providers while Aetna processes recredentialing applications. There is no difference in how M/S and MH/SUD recredentialing applications are processed, and the same team handles both types of applications.

Taken together and in the aggregate, all of these outcome data elements demonstrate the same or lower denial rates and similar processing turnaround times for MH/SUD providers compared to M/S providers. This analysis demonstrates that in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying credentialing to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying credentialing to M/S benefits.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As noted in Step 1, credentialing or an equivalent assessment applies to all M/S and MH/SUD benefits delivered in network, including the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient, both office and all other; and 3) emergency services when provided by an in-network provider. Step 2 identified the factors that are used in the design and application of Aetna's credentialing programs, including with respect to: 1) the procedure for performing credentialing and recredentialing; 2) credentialing practitioners; and 3) credentialing and assessing organizational providers. Step 3 explained the evidentiary standards and sources for those factors, and how they are used in the design and application of credentialing. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD providers or services. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD providers subject to credentialing or an equivalent assessment and concluded that there are no written differences in that application that results in any MH/SUD services being treated more stringently than, or incomparably to, M/S services. Finally, Step 5 demonstrated that, in operation, M/S and MH/SUD providers applying to join the network are credentialed in a comparable manner, and credentialing applications are reviewed substantively and administratively in a comparable and no more stringent manner.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors in designing and applying credentialing with respect

to MH/SUD and M/S providers. As noted in Step 2, Part 1, the factors used in the design of credentialing are: 1) quality care and service to members and 2) operation of the NQOC and related groups, both of which are general design factors that are applied the same and comparably, as written, to M/S and MH/SUD services. These design factors do not distinguish between, and are applied the same to, both M/S and MH/SUD benefits. The underlying evidentiary standards of NCQA and URAC guidelines apply to both M/S and MH/SUD providers, and Aetna implements these guidelines through QM policies and procedures, adopted by the NQOC (which includes both MH/SUD and M/S representation), that apply to both M/S and MH/SUD providers.

In the application of credentialing, Aetna applies the same internal Network and QM policies and procedures in the process of credentialing and recredentialing for M/S and MH/SUD providers. Further, the application factors for practitioners apply to both M/S and MH/SUD practitioners, and the application factors for organizational providers apply to both M/S and MH/SUD organizational providers. For practitioners, the same factors and evidentiary standards of 1) provider qualifications; 2) sanction and exclusion information; and 3) history of professional competence and conduct are used to evaluate the M/S and MH/SUD providers applying to join the network. Furthermore, the same factors and evidentiary standards are applied to admit organizational providers to Aetna's network through Aetna's organizational provider credentialing and assessment processes. In both processes, the M/S or MH/SUD organizational provider is evaluated based on the same criteria: 1) state and federal regulatory requirements; 2) business requirements; and 3) accreditation.

As demonstrated in Step 5, an in-operation review of Aetna's credentialing activity shows comparable MH/SUD and M/S practitioner and organizational provider application denials in calendar year 2025. The turnaround time results show that Aetna took a similar amount of time to process MH/SUD provider applications compared to M/S applications. This in-operation data demonstrates that credentialing is not applied more stringently to MH/SUD providers.

From this information, Aetna concludes that, both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply credentialing with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply credentialing with respect to M/S benefits across all applicable benefit classifications. Taken together, the factors, sources, and evidentiary standards, as well as the written materials and in-operation analysis, demonstrate that the credentialing NQTL is applied comparably and no more stringently to MH/SUD benefits than M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Senior Analyst, Network and Provider Data Services, Credentialing Verification Operations • Senior Manager, Health Care Quality Management, National Quality Management

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Virginia Mental Health Parity and Addiction Equity Act (MHPAEA) Nonquantitative Treatment Limitations (NQTL)

PROVIDER DIRECTORIES – IN-NETWORK

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of participating provider directory and* ***(2)*** *an identification of all medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits to which participating provider directory applies and a description of the benefits classifications to which the M/S and MH/SUD benefits subjected to the NQTL belong*

Step 1, Part 1. Identification of the NQTL: Provider Directory [45 CFR 146.137(c)(1)(i)]

The provider directory[1] is Aetna's comprehensive listing of contracted network health care providers and facilities. The provider directory is available to members and the public in both online and paper formats. The directory serves as a resource for locating participating medical, behavioral health, substance use disorder, and facility providers, and includes key information such as provider names, specialties, office locations, contact information, languages spoken, gender, and whether new patients are being accepted. Facility listings include facility names, addresses, contact information, and types of services offered.

The provider directory information described in this analysis is applied uniformly to both professional and facility providers. Because the factors, evidentiary standards, strategies, and processes do not differ based on provider type, the information is presented on a combined basis rather than separately.

Aetna utilizes multiple vendors and internal teams to support provider data management, credentialing activities, and provider directory production.

- Credentialing Services: Credentialing functions are supported by Cognizant, which assists with the provider credentialing processes and related data maintenance activities.
- Provider Data Services (PDS): The day-to-day maintenance and updating of provider demographic and directory data is managed through the Provider Data Services (PDS) organization. PDS utilizes Sutherland and EXL to perform provider data updates, validation, and ongoing maintenance activities to support directory accuracy.
- Provider Data Governance: The Provider Data Governance team is responsible for oversight of provider data quality and the generation of provider directories. Production

[1] Respectfully, Aetna disagrees that "Provider Network Directory" constitutes a non-quantitative treatment limitation, as provider network directories are not "limitations that are not expressed numerically but otherwise limit the scope of duration of benefits for treatment" as contemplated by MHPAEA or its implementing regulations. Aetna further objects on grounds of vagueness. Subject to and without waiving this objection, Aetna is committed to maintaining accurate, useful provider network directories that meet all legal requirements, and provides the requested information herein.

and distribution of paper provider directories are supported by Command Marketing Innovations (CMI) under a contractual arrangement with Aetna.

- Provider Data Validation: LexisNexis serves as Aetna's provider data validation vendor. On a routine cadence, Aetna submits provider location information displayed in the directory to LexisNexis for verification. LexisNexis compares the submitted information against its proprietary data sources and returns validation results indicating varying levels of confidence regarding the accuracy of the provider's directory information. When validation results indicate a low level of confidence that a provider is actively practicing at a listed location, Aetna engages Concentrix to conduct outreach calls and verify the publicly available provider directory information. Based on the validation results obtained through Concentrix, Aetna reviews the findings and determines whether updates are necessary. If updates are warranted, requests are submitted to PDS for processing through established provider data maintenance procedures.

While responsibilities are shared among internal departments and external vendors, Aetna maintains oversight and accountability for provider directory accuracy, data governance, and compliance with applicable regulatory requirements. Vendor-specific activities are performed in accordance with Aetna's established provider data management, credentialing, and directory maintenance processes and procedures

Aetna maintains a paper provider directory, available in hard copy upon request. The paper directory is updated quarterly. The online directory is public and can be accessed without creating an account or entering a policy number (https://www.aetna.com/VA Directory of Health Care Professionals). There is one directory that includes both M/S and MH/SUD providers and it is not separated by benefit classification. The online directory is updated 6 days a week, excluding holidays, Sundays, or interruptions due to system maintenance, upgrades, or unplanned outages.

For providers who are directly credentialed by Aetna, provider information is sent to the Provider Data Services (PDS) team upon completion of the credentialing process. Approximately 85% of providers are added to the provider directory within 10 business days after the credentialing information is received and processed. Directory updates are then incorporated through scheduled system refreshes, which typically occur within 3 to 4 business days. For providers associated with delegated entities or certain hospital-based arrangements, the delegated entity is responsible for credentialing and submits provider rosters to Aetna for directory inclusion. Once the roster information is received, validated, and processed, providers are added to the directory through the standard update process.

Providers must be credentialed before being added to the provider directory.

- For directly credentialed providers, Aetna completes the credentialing process prior to directory inclusion.
- For delegated provider groups and entities, the delegated organization is responsible for credentialing providers according to Aetna's credentialing standards and requirements before submitting providers for inclusion in the directory.
- Cognizant supports credentialing activities as an extension of Aetna's internal credentialing team and follows the same processes, systems, and standards established by Aetna.

Following successful credentialing and receipt of the provider information by the PDS team, approximately 85% of providers are added to the provider directory within 10 business days. Directory refresh processes generally occur within 3 to 4 business days.

Providers are not added to the directory while the initial credentialing application is still in process.

The provider must first complete the credentialing process and be approved before being included in the provider directory. Initial credentialing is generally completed within approximately 30 days, after which the provider information is submitted for directory inclusion.

Once a provider termination is received, validated, and approved for processing, the provider is removed through the directory update process. Approximately 85% of provider data changes, including terminations, are reflected in the provider directory within 10 business days.

Routine recredentialing does not result in the provider being removed from the directory. Providers remain listed while the recredentialing process is underway. However, if a provider fails to comply with recredentialing requirements and the appropriate review and committee processes result in a termination decision, the provider will be removed from the directory in accordance with the standard termination process described above.

Updates are triggered by providers notifying Aetna of changes to their information, as well as Aetna conducting targeted reviews and directory audits. Providers may use the provider portal, Availity or submit an online form to notify Aetna of corrections to their provider data at **Aetna.com**.

Regardless of whether they are physicians, psychologists, social workers, nurse practitioners, physician assistants, or other licensed practitioners, providers are displayed in the directory using the same overall format and search experience. Provider listings include applicable demographic, credential, specialty, and location information regardless of provider type. Certain fields may vary based on the provider category. For example, facility listings may include information specific to facilities that would not apply to individual practitioners.

The provider information is maintained in the same database for both the print and online directories, for both M/S and MH/SUD providers and facilities. For both print and online directories, only contracted providers are listed. The information displayed in the directory varies based on whether the listing is for an individual practitioner or a facility/group practice, reflecting the different types of information relevant to each provider type.

For individual providers, the directory includes the provider's:

- Name
- Specialty
- Gender
- Whether they are currently accepting new patients
- Address and contact information for each office location
- Any languages spoken by the provider other than English

Additionally, providers may voluntarily include additional information, including information such as race, ethnicity, and cultural preferences. However, Aetna does not require providers to supply their personal demographic information.

For facility providers including pharmacies, the directory includes the facility name, address, the types of services provided by the facility, and contact information.
The directory includes information about referrals and special exceptions for providers not in the network. The full directory is also available in Spanish. Accessibility information for individuals with disabilities are provided, as well as language assistance for those with limited English proficiency. There is also a web link under each provider entry to "Report Incorrect Provider Info."

The directory excludes certain hospital-based providers who typically do not maintain

independent appointment schedules for members. These provider types include radiologists, anesthesiologists, pathologists, and emergency room (ER) providers. Because members generally cannot directly schedule appointments with these providers, they are not individually listed in the directory. Facility listings remain available to help members identify participating hospitals and care locations.

In most cases, both the facility and the individual professional provider are listed separately in the provider directory. Providers who actively see and treat patients are generally displayed as individual directory entries in addition to their affiliated facility. An exception may apply when contractual or payment arrangements specify that services are billed and reimbursed exclusively under the facility or group entity. In those circumstances, directory listing practices may be adjusted accordingly. Otherwise, both the facility and the individual provider are listed to help members identify and locate the specific practitioners from whom they may receive care.

Below is a complete list of the unique specialty practitioner types and facility types listed and searchable in the provider network directory. Within each of the listed categories, there is a list of facility types, which are noted with an *:

M/S Facility Types Listed:

- Hospitals
- Outpatient Treatment & Facilities
- Therapy & Rehabilitation
- Dialysis Centers
- Hearing Center

M/S Facility Types Searchable

- Acute Short Term Hospital*
- Acute Rehabilitation Facility*
- Ambulatory Surgicenter*
- Birthing Center*
- Blood Banking/Transfusion
- Children's Hospital
- Diabetic Treatment Center*
- Diagnostic Radiology Center
- Diagnostic Testing Center*
- Durable Medical Equipment*
- Freestanding Emergency Center
- Home Health Agency
- Hospice (Freestanding)
- Hyperbaric Medicine*
- Infusion Center*
- Laboratory*
- Long Term Acute Care Hospital
- Mobile Units (Mammography, Bone Density, Lithotripsy)
- MRI Center*
- Occupational Medicine Clinic*
- Oncology Treatment Center*
- Optical Facility*
- Orthotics & Prosthetics Facility*
- Pain Management Center*
- Physical Therapy Center*
- Rehabilitation Hospital

- Rural Health Center
- Skilled Nursing Facility*
- Sleep Diagnostic Center*
- Speech Pathology Center
- Speech Therapy Center*
- Voluntary Interruption of Pregnancy Center*
- Urgent Care Center*
- Walk-In/Retail Clinic*

Pharmacy Types:

- Retail
- Mail Order
- Specialty

M/S Provider Types Listed:

- Adolescent Medicine Physician
- Family Practice Physician
- General Practice Physician
- Geriatrician
- Internist
- Pediatrician
- Acupuncturist
- Audiologist
- Cardiologist
- Chiropractor
- Dermatologist
- Endocrinologist
- Gastroenterologist
- General Surgeon
- Geriatrician
- Gynecologist
- Internist
- Neurologist
- Neurosurgeon
- OB-GYN (Obstetrics/Gynecology and Nurse Midwife)
- Occupational Therapist
- Oncologist
- Ophthalmologist
- Optometrist
- Oral Surgeon
- Orthopedist
- Otolaryngologist (ENT)
- Pediatrician
- Pediatric Internist
- Physical Therapist
- Podiatrist
- Pulmonologist
- Radiologist
- Rheumatologist
- Urologist

The online provider directory includes the ability to search by common conditions and procedures. Search results can also be filtered to identify providers offering telemedicine

services.

MH/SUD

Below is a complete list of the unique specialty practitioner types and facility types searchable in the provider network directory. For facilities, the types displayed are “Mental Health Facilities,” “Substance Use Facilities,” and “Eating Disorder Facilities.” Clicking on any of these will show these facility types that treat those conditions.

MH/SUD Facility Types Listed:

- Mental Health Facilities
- Substance Use Facilities
- Eating Disorder Facilities

MH/SUD Facility Types Searchable:

- Acute Short Term Hospital
- Community Mental Health Center
- Crisis Stabilization Center
- Eating Disorder Facility
- Intensive Outpatient Program
- Partial Hospital/Day Programs
- Psychiatric Hospital, Acute and Long Term
- Residential Treatment Facility
- Substance Abuse Facility

Each MH/SUD facility listing includes the levels of care offered, the age group treated, as well as the type of service.

MH/SUD Facilities include the level of care offered:

- Inpatient
- Residential
- 23 Hour Observation
- Partial Hospitalization
- Intensive Outpatient
- Outpatient

And the age group treated:

- Child
- Adolescent
- Adult
- Geriatric

As well as the type of service:

- Autism
- Crisis Stabilization
- Detox
- Eating Disorder
- Electroconvulsive Therapy
- Methadone Ambulatory Detox
- Methadone Maintenance
- Psychiatric
- Suboxone Services
  Substance Abuse
  Support Living Psychiatric

Support Living Substance Abuse

Pharmacy Types:

- Retail
- Mail Order
- Specialty

MH/SUD Provider Types based on the provider's license:

- Applied Behavior Analysis
- Certified Addictions Counselor
- Clinical Psychologist
- Clinical Social Worker
- Drug and Alcohol Counselor
- Licensed Professional Counselor
- Marriage and Family Counselor
- Neuropsychologist
- Pastoral Counselor
- Physician Assistant - Behavioral Health
- Psychiatric Nurse
- Psychiatrist
- Psychological Examiner

MH/SUD Focus Areas: MH/SUD providers indicate which focus areas apply to their practice, and these are searchable and filterable in the online directory. The provider types and focus areas that are separately displayed in the directory are indicated with an *. Additionally, the common conditions listing include depression and anxiety disorders, allowing members to access providers in either the Mental Health display or the Common Conditions display.

- Addiction Medicine
- Addiction Psychiatry
- Addictionology
- Addictions Specialist
- Adolescent Psychology
- Anxiety and Stress Management Counseling*
- Anxiety Disorders*
- Applied Behavioral Analysis
- Attention Deficit Disorder
- Attention Deficit Hyperactivity Disorder (ADHD) *
- Autism Spectrum Disorder*
- Behavioral Health Services Telehealth
- Biofeedback
- Certified Employee Assistance Professional (CEAP cert req)
- Child Abuse
- Child and Adolescent Specialist*
- Child Psychiatry
- Child Psychology
- Christian Counseling*
- Codependency Issues
- Cognitive Behavioral Therapy*
- Crisis Intervention
- Depression*
- Detox
- Developmental Behavioral Pediatrics
- Developmental Medicine
- Dialectic Behavioral Therapy*
- Dissociative Disorder
- Domestic Violence*
- Drug, Alcohol, and other Addictions*
- Eating Disorder Specialist*
- Forensic Psychiatry
- Gender Identity*
- Geriatric Counseling*
- Grief Counseling*
- Group Therapy
- Health/Physical Disabilities*
- Learning Disabilities
- Life Management Counseling
- LGBTQIA*
- Marriage/Family Focus*
- Men's Issues
- Mindfulness
- Mood Disorders
- Neuropsych Testing
- Obsessive-Compulsive Disorder*
- Parenting Issues*
- Personality Disorders
- Pharmacological/Medication Management*
- Post-Traumatic Stress Disorder*
- Psychiatry*

- Psychiatry, Child & Adolescent
- Psychiatry, Geriatric
- Psychological Testing*
- Psychotic Disorders
- Sexual/Child Abuse*
- Suboxone Certified - Prescriber Behavioral Health*
- Suboxone Certified -Prescriber
- Substance Abuse Professional (SAP certification required)
- Transcranial Magnetic Stimulation*
- Women's Issues

Telehealth and virtual programs: Provider search results can be filtered on local providers who offer telemedicine services. Additionally, Aetna maintains a page within the provider directory with information on nationally available telehealth and virtual MH/SUD groups. These are categorized as follows:

- Depression, anxiety, or those struggling with mental well-being concerns
- Struggling with suicide
- Substance and alcohol use concerns
- Chronic medical conditions and mental health
- Serious mental health conditions
- Eating disorders
- Obsessive-compulsive disorder

1. Plan Documents:

Virginia's standard certificate of coverage provides:

Certificate of Coverage – VA AL HCOC 14

[Providers
[Our **[provider]** network is there to give you the care you need. The easiest way to find **[providers]** and see important information about them is by logging in to your member website. There you'll find our online **[provider]** directory. You can also call the toll-free number on your member ID card to obtain the information or request a printed directory. See the *Contact us* section for more information.

You choose a **[PCP]** to oversee your care. Your **[PCP]** will provide routine care and send you to other **[providers]** when you need specialized care. Your plan often will pay a bigger share for **covered services** you get through your **[PCP]**, so choose a **[PCP]** as soon as you can.]

[Our [designated] and [non-designated] **[provider]** network is there to give you the care you need. You can find **network [providers]** and see important information about them by logging in to your member website. There you'll find our online **[provider]** directory. You can also call the toll-free number on your member ID card to obtain the information or request a printed directory. See the *Contact us* section for more information. You choose a [designated] network **[PCP]** to oversee your care. Your **[PCP]** will provide routine care and send you to other **[providers]** when you need specialized care.

[You may not select a **[non-designated] network [provider]** as a **[PCP]** unless authorized by us with a special **referral**.]]

[You don't have to get care through your **[PCP]**. You may go directly to other **network [providers]**.] [Your plan often will pay a bigger share for **covered services** you get through your **[PCP]**, so choose a **[PCP]** as soon as you can.]

For more information about the network and the role of your **[PCP]**, see the *Who provides the care* section.]]

Network [providers]
We have contracted with **[providers]** [in the service area] to provide **covered services** to you. These **[providers]** make up the network for your plan.

To get network benefits, you must use **network [providers]**. There are some exceptions:

- **Emergency services** – see the description of **emergency services** in the *Coverage and exclusions* section.
- [Non-emergency surgical or ancillary services provided by an **out-of-network [provider]** at a **network** facility.
- **Out-of-network** air ambulance services.]
- [Urgent care – see the description of urgent care in the *Coverage and exclusions* section.]
- [**Network [provider]** not reasonably available – You can get services from an **out-of-network [provider]** if an appropriate **network [provider]** is not reasonably available. You must request approval from us before you get the care. Contact us for assistance.]
- Transplants – see the description of transplant services in the *Coverage and exclusions* section.

You may select a **network [provider]** from the online directory through your member website.

You will not have to submit claims for services received from **network [providers]**. Your **network [provider]** will take care of that for you. And we will pay the **network [provider]** directly for what this plan owes.]]

2. Policies, Procedures and Provider Materials

Policies and Procedures:

Aetna applies the following internal policies and procedures in developing and maintaining the provider directory:

- Aetna Online Provider Search Policy and Procedure
- Network and Provider Data Services (NPDS) Data Validation and Quality - Proactive Outreach Validation Procedure: P300-271.000

And these policies in collecting and verifying provider information:

- QM 51: Assessment of Organizational Providers
- QM 53: Credentialing Allied Health Practitioners
- QM 53: Credentialing Allied Health Practitioners - Virginia Amendment
- QM 54: Practitioner Credentialing/Recredentialing Policy
- QM 54: Practitioner Credentialing/Recredentialing Policy - Virginia Amendment
- QM 56: Practitioner Application Policy

Provider Manual:

Provider manual (https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/office manual hcp.pdf)

Provider data Updates

Federal and state law requires Aetna and providers to work together to maintain accurate provider directory lists.

The law requires you and Aetna to keep your information current and to confirm its accuracy at least every ninety (90) days. However, Aetna may require confirmation upon request as well.

Updating your data

Our provider directories include provider data information to help patients find care. Being in our directories allows new patients to find out if you are accepting new patients, where you're located, and how to reach you. Additionally, by making sure we have your current information, we can send you timely communications and reminders.

Remember to notify us of your data changes. Failure to do so will result in corrective action in accordance with your agreement with us and applicable law.

Here is how to update your information

Go to **Availity.com**, to update your information. (If you can't use **Availity.com**,, submit a Request Changes to Provider Data Submission Form found on **Aetna.com**.) Here are some examples of information you can update:

- Primary address indicator
- Service location address
- Provider name
- Appointment phone
- Accepting new patients
- Specialty
- Handicap accessibility
- Office hours
- NPI
- Gender
- Language
- Board certification
- Education/degree
- Hospital affiliation
- Office staff language
- Race
- Ethnicity

Step 1, Part 2. Applicable M/S and MH/SUD Benefits and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Overview

Provider Directory information applies to M/S and MH/SUD benefits in the following benefit classifications: **in-network inpatient**; **in-network outpatient- all other**, and **in-network outpatient office visit**

Benefits and Classification

Benefit classifications to which NQTL applies:	**✔ INN IP ✔ INN OP AO ✔ INN OP OV**
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
Any services that can be performed by the providers included in the directory	Any services that can be performed by the providers included in the directory

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146-137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of the provider directory. Each subpart includes:* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the provider directory, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factor (qualitative) and the accompanying evidentiary standards and sources considered or relied upon in the creation and design of the provider directory.

Factor	Applicable to M/S	Applicable to MH/SUD
Specificity and Accuracy of Provider Directory Information	✓	✓

- **Specificity and Accuracy of Provider Directory Information** is the **factor** used to create and maintain the provider directory. This factor ensures that provider and facility information is complete, current, accurate, and sufficiently detailed to enable members to make informed healthcare decisions and access covered services. The provider directory relies on information submitted by contracted providers and facilities, as well as verification activities performed by Aetna to confirm the accuracy of the information displayed to members. The evidentiary standards and sources upon which this factor is based are:
  - Applicable Federal law
  - Applicable State law
  - Information provided by contracted providers and facilities
  - Verification of information provided by contracted providers

The state and federal law factors are weighted more than the information provided by providers factor in the creation of the provider directory. Providers must share the minimum information required for credentialing verification and as required by state and federal law, but additional information (race, ethnicity, email addresses) is voluntary. Without this minimum information, providers cannot be credentialed and will not appear in the provider directory. Therefore, this factor is weighted more than the voluntary information providers may submit. Providers may choose to submit additional personal information (race, ethnicity, email addresses). This is voluntary and will provide

additional detail in a directory listing, but it is not required. Therefore, this factor is weighted less than the mandatory directory elements.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factor and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL for designing and maintaining Aetna's preferred provider directory.

(a) Directory Display and Searchability, and Navigation Assistance

Factor	Applicable to M/S	Applicable to MH/SUD
Identification of the specialties, facility types, and services most frequently searched by members and selected for appointments	✓	✓
Identification of the conditions and procedures most frequently searched by members	✓	✓
Member experience and usability testing	✓	✓
Online Accessibility	✓	✓
Language assistance	✓	✓

- **Identification of the specialties, facility types, and services most frequently searched by members and selected for appointments** and **Identification of the conditions and procedures most frequently searched by members** are **factors** used to apply the information supplied by providers. To maximize members' ability to find the care they need, Aetna uses internal search analytics and claims data to identify the provider types, facilities, services, conditions and procedures most often searched and selected for appointments. All in-network providers remain searchable, while the directory's category navigation highlights the provider and facility types most relevant to member appointment needs.
- **Member experience and usability testing** are used to evaluate the provider directory's readability, content organization, and ease of navigation. Insights from this testing help ensure the directory is intuitive and accessible for members seeking care.
- **Online accessibility** is a key consideration in the design of Aetna's digital experiences. The provider directory is developed to support inclusive access for individuals with disabilities, helping ensure members can easily find and use the information they need.
- **Language assistance** is available to support members with diverse language needs. The provider directory can be searched online in English and Spanish, printed directories in additional languages are available upon request, and contact information for customer service in languages other than English is provided on the directory page.

No factor is weighted more than another factor.

Step 3: Description of How Factors are Used in the Design and Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45CFR 146.137(c)(3)]

The evidentiary standards and sources for each factor are as follows:

Specificity and Accuracy of Provider Directory Information

1. Applicable Federal law -

   Evidentiary Standards and Sources:

   a. Aetna complies with all applicable law related to its provider directories and applies the same to all applicable contracted providers (individuals, groups, clinics, and facilities) and only contracted providers.
   b. ERISA, added by the CAA of 2021, which provides, *inter alia,* the directory must include the names, addresses, specialty, telephone numbers, and digital contact information of individual health care providers, and the names, addresses, telephone numbers, and digital contact information of each medical group, clinic, or facility contracted to participate in any of the networks of the group health plan or health insurance coverage involved
2. State law -

   Evidentiary Standards and Sources:

   a. Aetna complies with all applicable state laws related to its provider directories and applies the same to all applicable providers on the carrier's panel.
   b. Applicable Virginia law, including 14VAC5-405-70

3. Information provided by contracted providers and facilities

   Evidentiary Standards and Sources:

   a. Information provided by contracted providers and facilities includes information both required by law and not required by law, but providers can voluntarily share and will give members additional information in directory entries.
   b. The applicable threshold is the information required in a credentialing or re-credentialing application. Additionally, voluntary information is accepted to give more information about providers but is not required. This applies to all providers

and facilities.

c. Credentialing information is generally collected through the Council for Affordable Quality Healthcare (CAQH) ProView, where providers enter their information including education, board certifications, work history, and demographic information. Providers can share additional information beyond what is required in a credentialing application directly with Aetna, either through their Network Management contact or online through the provider portal, Availity

4. Verification of information provided by contracted providers

Evidentiary Standards and Sources:

a. Aetna maintains policies to conduct activities to verify the information provided by Providers for inclusion in the provider directory; such policies are applied to all providers and facilities.
b. Aetna policies, including credentialing policies, and data validation and audit policies. Specific standards include state and federal statutory requirements referenced above, NCQA sampling methodology, and primary source verification through various applicable entities and databases

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

Directory Display and Searchability, and Navigation Assistance

1. Identification of the most common specialties, facility types, and services members search for and make appointments with.

Evidentiary Standards and Sources:

a. Maximization of opportunity to meet member health search needs. The directory includes many provider and facility types, only excluding certain hospital-based providers who typically do not maintain independent appointment schedules for members. These provider types include radiologists, anesthesiologists, pathologists, and emergency room (ER) providers. Because members generally cannot directly schedule appointments with these providers, they are not individually listed in the directory.
b. Internal Aetna search analytics and claims activity

2. Identification of the most common conditions and procedures members search for.

Evidentiary Standards and Sources:

a. Maximization of opportunity to meet member health search needs. The directory includes a list of common conditions and procedures members may search for providers to treat. This includes MH/SUD conditions and procedures in the Mental Health tile as well as two MH conditions in the Common Conditions tile.
b. Internal Aetna search analytics and claim activity.

3. Member experience and usability testing

Evidentiary Standards and Sources:

a. Aetna evaluates the directory for reading level, intuitive content organization, and ease of navigation.
b. NCQA NET 5, Physician and Hospital Directories, Element I

4. Online Accessibility

Evidentiary Standards and Sources:

a. All digital experiences. All digital experiences are designed to be inclusive and accessible to individuals with disabilities.
b. Web Content Accessibility Guidelines and Principles of Inclusive Design (https://www.w3.org/TR/WCAG21/)

5. Language assistance

Evidentiary Standards and Sources:

a. Directories and directory assistance is available in multiple languages. The online search is available in Spanish and English and print copies in other languages is available upon request. Telephone numbers to reach customer service in languages other than English are posted at the bottom of the directory page.
b. NCQA NET 5, Physician and Hospital Directories, Element I

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]
*This Step 4 demonstrates that, under the terms of the plan, **as written**, the processes, strategies, evidentiary standards and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts: **(1)** design and **(2)** application. Within each such discussion, this Step 4 addresses **(a)** documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification, **(b)** in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL, **(c)** documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and **(d)** as applicable, an explanation of any deviations or variations in the application of a factor*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

The provider directory information described in this analysis applies equally to both professional and facility providers. As the factors, evidentiary standards, methodologies, and processes used for provider directory management do not vary by provider type, the information has been presented on a combined basis rather than separately for professional and facility providers.

Aetna's analysis of the "as written" strategies in place to provide its members with an accurate directory that includes all information required by law, that is organized and searchable in a way to help members find the information they need, and to maintain the accuracy of that directory information, shows that those strategies are applied comparably to M/S and MH/SUD services and are not more stringently designed or applied to MH/SUD services than to M/S services. Specifically, in addition to the state and federal requirements for directory information, Aetna applies the

following internal policies and procedures in developing and maintaining the provider directory:

- Aetna Online Provider Search Policy and Procedure
- Network and Provider Data Services (NPDS) Data Validation and Quality - Proactive Outreach Validation Procedure #: P300-271.000

And these policies in collecting and verifying provider information:

- QM 51: Assessment of Organizational Providers
- QM 53: Credentialing Allied Health Practitioners
- QM 53: Credentialing Allied Health Practitioners - Virginia Amendment
- QM 54: Practitioner Credentialing/Recredentialing Policy
- QM 54: Practitioner Credentialing/Recredentialing Policy - Virginia Amendment
- QM 56: Practitioner Application Policy

Together, these polices represent the "written" strategies and processes Aetna employs to provide members with an accurate, complete, and usefully organized network provider directory relative to both MH/SUD and M/S services.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

Specifically, the Online Provider Search Policy and Procedure outlines the process by which the online directory is created to meet the requirements of all applicable state and federal legislation, as well as incorporating search functionalities that maximize opportunities to meet member health needs. The policy applies to both M/S and MH/SUD providers, and addresses the provider types included, the search functionality, reporting of directory inaccuracies, whether the provider is open/closed to new patients/members, and the schedule for updates. The policy outlines that the online directory includes categories of providers which are searchable, which includes a specific category for Behavioral Health, including clinical psychologists, clinical social workers, marriage/family therapists, and licensed professional counselors, and MH/SUD facilities. The policy lists the additional information that can be included for providers, such as the telemedicine indicator, hours of operation, and email address. The Online Provider Search Policy and Procedure addresses how Aetna complies with the NCQA NET 5 guidelines, which set standards for physician and hospital directories, including data, updates, assessment of accuracy, the searchable web-based directory, usability testing every three years, and availability of directories. Many of these elements are the same as the state and federal directory requirements; additionally, Aetna evaluates its web-based directory for understandability and usefulness to members and prospective members considering reading level, intuitive content organization, ease of navigation, and directories in additional languages as applicable to the membership.

Aetna's credentialing policies, discussed below, discuss the process for obtaining information from providers and facilities, and verifying that information, as well as the other opportunities and avenues for providers and facilities to submit information to Aetna for use in the directory. Specifically, QM 56 lists the minimum data elements for credentialing and re-credentialing practitioners, and QM 54 lists the criteria that require primary source verification, as well as the timeliness of the data and signature. For both M/S and MH/SUD Allied Health Professionals, which

are independent health care practitioners other than physicians, chiropractors, and podiatrists, QM 53 is the written policy for the provider information required and verification process. Additionally, QM 51 defines the criteria required and method for assessing facilities and ancillary providers. These policies apply equally to M/S and MH/SUD practitioners.

Aetna's Procedure #P300-271, Data Validation and Quality - Proactive Outreach Validation, defines the guidelines Aetna's NPDS utilizes to validate the accuracy of provider directory information. Although this procedure is developed to comply with CMS requirements for

directory requirements, this process applies to all Aetna network providers and applies equally to M/S and MH/SUD providers. This is a targeted proactive review performed quarterly based on information collected from Aetna's data validation vendor (LexisNexis) coupled with claim activity to determine whether Aetna has "high," "medium" or "low" confidence that the provider is active. As described in the procedure, provider locations with low and medium confidence are targeted for outreach to confirm their status. Providers are updated or removed according to the information received from the outreach calls.

Aetna's analysis of the "as written" strategies in place related to the specificity and accuracy of provider directory information, and to directory display, searchability, and navigation assistance shows that those strategies are applied comparably to M/S and MH/SUD services and are not more stringently designed or applied to MH/SUD services than to M/S services. Since the processes and policies are the same, these strategies are applied comparably to M/S and MH/SUD services and are not more stringently designed or applied to MH/SUD services than to M/S services.

<u>Step 5</u>: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

Aetna's analysis of the "in operation" strategies in place relating to the specificity of the directory and display and searchability of various specialty, subspecialty, facility types, and specific services shows that those strategies are applied comparably to M/S and MH/SUD services and are not more stringently designed or applied to MH/SUD services than to M/S services. In operation, the online directory includes a free text search box, making any specific provider (i.e. Dr. John Smith) or any specialty searchable by either the clinical name or common name. The online directory also allows members to navigate to services by category; the initial directory page provides thirteen (13) categories, which include: 1) Medical Doctors and Specialists; 2) Hospitals and Facilities; 3) Urgent Care; 4) Walk-In clinics; 5) Pharmacy; 6) Dental Care; 7) Vision; 8) Labs and Testing; 9) Alternative Medicine; 10) DME; 11) Common Procedures and Conditions; 12) Institutes of Quality/Excellence, and a specific, dedicated category for Mental Health. Each of these categories then serves as a central resource for members requiring information related to that category. The Mental Health Category serves as a central source for all directory information pertaining to MH/SUD services. Users may navigate based on categories such as mental health professionals, facilities, telehealth, and employee assistance programs. If, for example, a user selects mental health professionals, they may then search for in-network individual providers based on various areas of concern which are the BH provider focus areas discussed in Step 1a. These include, for example, anxiety and stress management counseling, domestic violence, eating disorder specialist, gender identity, and drug, alcohol, and other addictions. Users can also search for facility types and telehealth options.

Specific services offered by a provider or facility are often implicit and clear from the description of the provider or facility's specialty or subspecialty, or facility type. However, for MH/SUD services, Aetna provider directories offer members a way to search for providers based on the provider's areas of focus which align to specific services and needs a member may seek to meet. By providing this dedicated central mental health resource, at minimum, Aetna provider directories offer members an ability that is at least equal to that for M/S services, to search for and identify specific MH/SUD providers and services based on a member's specific health concerns.

In operation, Aetna's directory accuracy audits apply equally to MH/SUD and M/S individual providers and facilities, and results are monitored in aggregate. Through the directory accuracy audits, Aetna updates the information listed in its provider directories. Proactive initiatives happening in 2025 on a national basis, include (Procedure P300-271.000)

- Increase the number and/or frequency of provider demographic system data audits to proactively identify errors or potential system set-up issues.
- Review and validate providers that are printing in a directory with more than 5 locations.
- Conduct a comparison between large provider entities' website, roster, and Aetna's provider database to identify inaccuracies.

For both (MH/SUD) providers and (M/S) providers, approximately 85% of provider directory updates (additions and removals) are completed within 10 business days of receiving the information required to process the change.

This timeframe is based on the standard Provider Data Services (PDS) process for managing provider directory updates. The measurement is derived from PDS time studies that evaluate the end-to-end workflow required to complete a provider data transaction. These studies account for the time needed to:

- Receive the provider information or update request
- Validate and verify the submitted information

- Process and update the provider record in the appropriate systems
- Publish the updated information to the provider directory through the regular directory refresh process

The 10-business-day timeframe reflects the average production cycle required to complete these activities and ensures that provider information is accurately validated, updated, and displayed in the directory. The same process and performance standards apply to both MH/SUD and M/S provider directory updates.

A review of our provider directory for providers serving the state of Virginia through September 2026 identified a total of 20,453 MH/SUD providers, of which 20,111 (98%) were accepting new patients. During the same period, the directory included 29,733 M/S providers, of which 28,763 (97%) were accepting new patients. These findings demonstrate a high level of provider availability for members seeking both MH/SUD and M/S services in Virginia.

To evaluate provider activity, Aetna reviewed Virginia-based providers listed in the provider directory and compared those providers against claims processed during the most recent six-month measurement period. For purposes of this analysis, an "actively submitting claims" provider is defined as a provider that had at least one claim processed within the previous six months. In addition, providers whose network effective date occurred within the previous six months were identified separately, as they may not have had sufficient time to submit claims or receive reimbursement.

For M/S providers, the directory included 29,733 providers. Of these, 25,333 providers (85.2%) had at least one claim processed within the previous six months and were therefore considered actively submitting claims. The remaining 4,400 providers (14.8%) did not have a processed claim during the measurement period; however, 711 of these providers were newly effective within the previous six months and are therefore not expected to have established claims activity or reimbursement history.

For MH/SUD providers, the directory included 20,453 providers. Of these, 13,829 providers (67.6%) had at least one claim processed within the previous six months and were therefore considered actively submitting claims. The remaining 6,624 providers (32.4%) did not have a processed claim during the measurement period; however, 937 of these providers were newly effective within the previous six months and are therefore not expected to have established claims activity or reimbursement history.

Recent claims submission and reimbursement activity were measured based on claims processed within the prior six months. Providers with at least one processed claim during this period demonstrated recent claims submission activity and recent reimbursement activity. Providers without claims processed during the six-month measurement period were not considered actively submitting claims for purposes of this analysis.

Aetna’s analysis demonstrates that, in operation, its strategies to provide members with an accurate, complete, and usefully organized network provider directory are applied comparably to M/S and MH/SUD services and are not more stringently designed or applied to MH/SUD services than to M/S services.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) Any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of §146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1,** Aetna maintains a single provider directory, which includes both M/S and MH/SUD providers. Current and prospective members can access the directory online or on paper, without a password or account. Searches can be conducted by name or provider type and can be filtered by various attributes such as gender, language, hospital affiliation, and whether the provider is accepting new patients. Aetna evaluates the online provider directory for understandability and usefulness to members and prospective members, including reading level, intuitive content organization, and ease of navigation. **Step 2** identified the factors used to develop and maintain the accuracy of provider directory, including factors relating to the specificity and accuracy of the provider directory information, and directory display and searchability, and navigation assistance. For both M/S and MH/SUD practitioners, the directory includes all information required by state and federal law, as well as additional information that may be voluntarily provided by a provider. The directory includes various organizational features and search functions to assist members in locating M/S and MH/SUD providers to fit their needs. ***Step 3*** explained in detail the evidentiary standards and sources the factors used to develop and/or maintain the accuracy and accessibility of the provider directory. ***Step 4*** then explained how those factors are applied, in writing, to M/S and MH/SUD services. Specifically, in addition to the state and federal requirements for directory information, Aetna applies internal policies and procedures in developing and maintaining the provider directory. As written, the written processes, strategies, evidentiary standards and other factors used to develop and maintain Aetna's provider directory demonstrate comparability between MH/SUD benefits and M/S benefits and are not applied more stringently. Finally, ***Step 5*** demonstrated that, in operation, Aetna's strategies to provide members with an accurate, complete, and usefully organized network provider directory are applied comparably to M/S and MH/SUD services and are not more stringently designed or applied to MH/SUD services than to M/S services. Based upon the provider directory design, Aetna assists its members in locating providers that can meet their MH/SUD needs just as easily as they can locate M/S providers. In sum, the factors, evidentiary standards and sources used

to develop, maintain and audit the provider directory are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.

Analysis Completed:	**September 30, 2026**
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Sr. Manager, Mental Health Parity Team

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Nonquantitative Treatment Limitation Comparative Analysis:

NETWORK ADEQUACY

Step 1: Description of the NQTL [45 CFR 146.137(c)(1)]

In accordance with 45 CFR 146.137(c)(1), this Step 1 provides a description of the NQTL in two Parts: ***(1)*** *an identification and description of network adequacy, and* ***(2)*** *an identification of all mental health/substance use disorder (MH/SUD) and medical/surgical (M/S) benefits to which network adequacy applies and a description of the benefits classifications to which the M/S and MH/SUD benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Network Adequacy [45 CFR 146.137(c)(1)(i)]

The network adequacy information described in this analysis are applied uniformly to both professional and facility providers. Because the factors, evidentiary standards, strategies, and processes do not differ based on provider type, the information is presented on a combined basis rather than separately. The operational data in step 5 is separated out by professional and facility provider types

Network adequacy refers to the ability of a health plan to provide members with timely access to a sufficient number of in-network providers, both M/S and MH/SUD. Aetna works to maintain sufficient numbers and types of M/S and MH/SUD providers in its network and implements standards for access to appointments for covered M/S and MH/SUD services. Aetna monitors how effectively its network meets the needs and preferences of its members through an evaluation of network availability, network accessibility, and additional procedures and measures set forth herein. Network availability refers to the extent to which practitioners of the appropriate type and number are geographically distributed to meet the needs of members. Network accessibility refers to members' ability to receive timely care for covered services from network providers (that is, to schedule an appointment). The following materials describe network adequacy:

1. Plan Documents

Virginia's standard certificate of coverage provides:

Certificate of Coverage, AL VA HCOC V014

[Providers

[Our **[provider]** network is there to give you the care you need. The easiest way to find **[providers]** and see important information about them is by logging in to your member

website. There you'll find our online **[provider]** directory. You can also call the toll-free number on your member ID card to obtain the information or request a printed directory. See the *Contact us* section for more information.

[Network [providers]
We have contracted with **[providers]** [in the service area] to provide **covered services** to you. These **[providers]** make up the network for your plan.

2. Provider Manuals

Aetna's participating providers are contractually required to comply with the terms contained in Aetna's Provider and Facility Participation Criteria and Provider Manuals. Aetna's Provider and Facility Participation Criteria include network accessibility requirements, which apply in the absence of more stringent standards established by applicable state law. These requirements are specific to each type of provider. Please see Appendix B for Provider Manual provisions applicable to network adequacy.

3. Policies and Procedures

Virginia does not have state specific network adequacy policies and procedures, therefore Virginia will follow the national policies described below. The following internal policies and procedures (P&Ps), which apply to M/S and MH/SUD benefits, address network adequacy:

- **QM 07: Member Access to Practitioner and Member Services Policy** defines the standards for M/S and MH/SUD practitioner appointment accessibility and establishes a mechanism for monitoring, evaluating, and managing member access to practitioners.
- **QM 10: Practitioner and Provider Availability: Network Composition and Contracting Plan** defines the minimum standards for M/S and MH/SUD network composition and establishes a process by which provider and practitioner availability standards are established and periodically assessed by the NQOC and used to improve network adequacy.
- **QM 87: Assessment of Network Adequacy P&P** provides the procedure for assessing network adequacy, including the procedure for identification of opportunities to improve network adequacy and evaluation of implemented activities for effectiveness.

Additionally, Aetna's **Quality Management (QM) Program Description**, which applies to M/S and MH/SUD benefits, outlines network adequacy, network availability, and network accessibility as components of the QM Program. This QM Program Description also details the accountability and committee structure for QM activities and provides the foundation for QM P&Ps.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits [45 CFR 146.137(c)(1)(ii)]; and Which Benefits are Included in Each Classification [45 CFR 146.137(c)(1)(iii)]

Benefits and Classification

Network adequacy applies to all M/S and MH/SUD benefits in the following benefit classifications: **in-network inpatient**; **in-network outpatient**, both **office** and **all other** subclassifications, and **emergency**.

Benefit Classifications to which NQTL Applies: ✔ **INN IP** ✔ **INN OV** ✔ **INN OP AO** ✔ **Emergency**	
M/S Services NQTL Applies to:	**MH/SUD Services NQTL Applies to:**
Applies to all M/S benefits delivered in-network	Applies to all MH/SUD benefits delivered in-network

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL [45 CFR 146.137(c)(2)]

In accordance with 45 CFR 146.137(c)(2), this Step 2 is addressed in two Parts: ***(1)*** *design, and* ***(2)*** *application of network adequacy. Each subpart includes:* ***(a)*** *identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to network adequacy, and* ***(b)*** *definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard). Notably, factors are "all information, including processes and strategies (but not evidentiary standards)" that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. 45 CFR 146.136(a)(2).*

Step 2, Part 1. Design of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design of the NQTL:

Factor	Applicable to M/S	Applicable to MH/SUD
Meeting the health care needs of members	✓	✓
Operation of the NQOC and related groups	✓	✓

- **Meeting the health care needs of members** is a **factor** and **strategy** providing a basis for Aetna's network adequacy standards and procedures. Meeting the health care needs of members encompasses efforts to provide members with timely access to a sufficient number of M/S and MH/SUD in-network providers for covered services, including primary care and specialty physicians, as well as other health care services included in the benefit contract. Aetna's Quality Management Program Description outlines components including network adequacy, network availability, and network accessibility, and also details the accountability and committee structure for QM activities. Aetna's NQOC establishes network adequacy standards and processes. The **evidentiary standards and sources** for this factor are:
    - NCQA Standards and Guidelines for the Accreditation of Health Plans, Network Management ("NCQA NET"), which provide guidance on maintaining sufficient numbers and types of practitioners in the network, monitoring how effectively the network meets the needs and preferences of the membership, maintaining appropriate access to services, and monitoring access to health care services.
    - In some states, an additional evidentiary standard and source for this factor is state network availability and accessibility standards. Where applicable, state-defined standards may include any or all of geographic travel distance standards, provider-to-member ratios, and appointment waiting time standards. In the design of the network adequacy NQTL, Aetna follows the most stringent of the applicable state or Aetna standard.

- **Operation of the NQOC and related groups** is another basis for Aetna's strategy in designing network adequacy. The National Quality Oversight Committee (NQOC) is a multidisciplinary committee composed of representatives from Aetna departments, which adopts the QM policies pertaining to the metrics and assessment of network adequacy, among other duties. These policies are developed by Aetna's National Quality Management Policy Team, which is the Aetna department involved in implementing and overseeing the policies related to network adequacy, in collaboration with Network Strategy and Provider Experience, which serves as a review body for all QM policies. The **evidentiary standards and sources** for this factor are:
    - NCQA Standards and Guidelines for the Accreditation of Health Plans, Quality Management and Improvement ("NCQA QI") and NCQA Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Quality Management and Improvement ("NCQA MBHO QI"), which provide requirements and guidance for a plan's quality improvement committee's composition and responsibilities.

Step 2, Part 2. Application of the NQTL – Identification and Definition of Factors, Evidentiary Standards, and Sources [45 CFR 146.137(c)(2)(i)-(ii)]

The following identifies and defines the factors and the accompanying evidentiary standards and sources considered or relied upon in the application of the NQTL. Network adequacy encompasses the components of: (a) network availability and (b) network accessibility, as well as additional components and processes through which the network is evaluated for adequacy, addressed in subsection (c).

(a) Factors for network availability

Factor	Applicable to M/S	Applicable to MH/SUD
Number of practitioners	✓	✓
Geographic distribution of practitioners	✓	✓

- **Number of practitioners** means Aetna measures the number of practitioners as a ratio to the number of members. This is expressed as a ratio of the count of providers of a certain type to the number of members and is calculated at the state level. The **evidentiary standards and sources** for this factor are:
    - NCQA NET 1: Availability of Practitioners, which is implemented through Aetna's policy QM 10: Practitioner and Provider Availability: Network Composition and Contracting Plan.
    - NCQA MBHO QI 3: Availability of Practitioner and Providers, which is also implemented through QM 10.
    - For states that set minimum provider counts, the state requirements supersede the Aetna QM 10 metrics. Aetna follows the stricter of the Aetna standard or the applicable state standard.
    - The ratios employed by Aetna are specific to the type of practitioner and are measured for high-volume and high-impact specialists for both M/S and MH/SUD, as well as other MH/SUD provider types and M/S primary care physicians. These are detailed in Appendix K.

- **Geographic distribution of practitioners** means Aetna measures the distance to a practitioner's office from the member's home. This is calculated for different provider types, with different standards based on population density (urban, suburban, rural). The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA NET 1: Availability of Practitioners, which is implemented through Aetna's policy QM 10: Practitioner and Provider Availability: Network Composition and Contracting Plan.

- NCQA MBHO QI 3: Availability of Practitioner and Providers, which is also implemented through QM 10.
- For states that set geographic or travel distance standards, the state requirements supersede the Aetna QM 10 metrics, Aetna follows the stricter of the Aetna standard or the applicable state standard.
- The population density standards have separate metrics established by urban, suburban, and rural ZIP codes, and are specific to the type of practitioner and are measured for high-volume and high-impact specialists for both M/S and MH/SUD, as well as other MH/SUD practitioners and M/S primary care physicians and other MH/SUD provider types. These are detailed in Appendix K.

(b) Factors for network accessibility

Factor	Applicable to M/S	Applicable to MH/SUD
Appointment waiting time	✓	✓

- **Appointment waiting time** means the length of time between a member's request for an appointment and when the practitioner can see them. This is measured by provider type and type of service required (routine, urgent/emergent, after hours). The **evidentiary standards and sources** upon which this factor is based are:
  - NCQA NET 2: Accessibility of Services, NCQA MBHO QI 4: Accessibility of Services, and CMS appointment timeliness standards, which are implemented through Aetna's policy QM 07: Member Access to Practitioner and Member Services Policy.
  - For states that set appointment wait time standards, the state requirements supersede the Aetna QM 07 metrics, Aetna follows the stricter of the Aetna standard or the applicable state standard.
  - The standards are specific to the type of provider and appointment, as detailed in Appendix K.

(c) Factors for network adequacy

Factor	Applicable to M/S	Applicable to MH/SUD
Review of accessibility and availability data	✓	✓
Assessment of member complaints	✓	✓
Assessment of member satisfaction survey	✓	✓
Assessment of utilization of out-of-network services	✓	✓

- **Review of accessibility and availability data** means Aetna analyzes the factors listed above in (a) network availability and (b) network accessibility in its annual network adequacy analysis. Data points are collected, analyzed, and trended to evaluate network adequacy. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network, which is implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure.
    - NCQA MBHO QI 3: Availability of Practitioner and Providers and QI 4: Accessibility of Services, which requires a review of data, that is also implemented through QM 87.
    - The minimum standards for each availability and accessibility metric are detailed in Appendix K.

- **Assessment of member complaints** related to network adequacy means Aetna reviews member complaints for trends. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network which is implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure.
    - NCQA MBHO QI 5: Member Experience (pertaining to network adequacy), which is implemented through QM 87.
    - Complaints are trended and analyzed year-over-year in Aetna's network adequacy analysis and compared against a standard or benchmark. The evidentiary standard triggering an additional review is 0.01 complaints per 1,000 member months and a volume of 5 or more in the calendar year, as required by QM 87 and adopted by the NQOC. If the complaints exceed this benchmark, Aetna conducts a qualitative analysis to examine the underlying reason for the results, including processes that may present barriers to improvement.

- **Assessment of member satisfaction survey** means Aetna evaluates the member experience using the provider network through member experience surveys administered by outside vendors. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network, which is implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure.
    - NCQA MBHO QI 5: Member Experience (pertaining to network adequacy), which is implemented through QM 87.
    - The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Adult Commercial Consumer Satisfaction survey is used to assess network adequacy for the M/S network, and the Behavioral Health Member Experience Survey is used to assess network adequacy for the MH/SUD network.

- **Assessment of utilization of out-of-network services** means Aetna analyzes requests for out-of-network services from utilization management data. The out-of-network rate is analyzed by type of service and trended year-over-year to identify trends. The **evidentiary standards and sources** upon which this factor is based are:
    - NCQA NET 3, Element A: Assessment of Member Experience Accessing the Network and NCQA MBHO QI 5: Member Experience (pertaining to network adequacy), which are implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure.

Step 3: Description of How Factors are Used in the Design or Application of NQTL [45 CFR 146.137(c)(3)]

In accordance with 45 CFR 146.137(c)(3), this Step 3 is addressed in two Parts: ***(1)*** *design and* ***(2)*** *application. Each subpart includes an explanation of:* ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *if applicable, if the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this subpart includes an explanation of the inter-relationship of the factors identified in Step 2.*

Step 3, Part 1. Design of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

- **Meeting the health care needs of members** is a factor used in the design of this NQTL as a basis for establishing network adequacy metrics and processes to assess the provider network.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in-network. Efforts to meet the health care needs of members, by working to provide members with timely access to a sufficient number of M/S and MH/SUD in-network providers for covered services, form a basis and rationale underlying Aetna's standards and procedures relating to network adequacy. These procedures include an annual assessment of network adequacy, identifying opportunities to improve the provider network, identifying barriers to network adequacy improvement, and implementing opportunities to improve the provider network.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards and sources relied upon in designing this NQTL are applicable state network adequacy standards and the NCQA Standards and Guidelines for the Accreditation of Health Plans and NCQA Standards and Guidelines for the Accreditation of Managed Behavioral Healthcare Organizations, Network Management, Availability of Practitioners (NCQA NET 1 and NCQA MBHO QI 3), Accessibility of Practitioners (NCQA NET 2 and NCQA MBHO QI 4), and Assessment of Network Adequacy (NCQA NET 3 and NCQA MBHO QI 3, QI 4, and QI 5). Some, but not all, states promulgate network adequacy standards. Where a state has promulgated such requirements, Aetna follows the most stringent standard as between its standards and the state law requirements for that jurisdiction.

These accreditation guidelines and standards, and any applicable state law requirements, are implemented through Aetna's QM policies listed in Step 1 and further explained in Step 4. These standards and policies apply equally to all M/S and MH/SUD benefits delivered in-network.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Operation of the NQOC and Related Groups** is a factor used as a basis for Aetna's strategy in the design of network adequacy.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in-network, as the groups discussed herein develop and approve policies and procedures that pertain to designing and assessing network adequacy. The NQOC is a multidisciplinary committee composed of representatives from Aetna departments: the Office of the Chief Medical Officer, Medical Directors, National Quality Management, Clinical Services, Behavioral Health Quality Management, Pharmacy Management, Network Management, Customer Service, Claims Processing, Complaints Grievances and Appeals, and National Accounts, among others, including Medicare departments and external participants. Adopting the QM policies pertaining to network adequacy is one duty of the NQOC and supports the committee's other initiatives, which is why representation is so extensive. Notably, the committee includes representation from Aetna's Behavioral Health business segment for all functions: Medical Directors, Network Management, Clinical Health Services, Customer Service, and Quality Management. The NQOC voting member roster is included in Appendix H.

The QM policies and procedures pertaining to the standards for and assessment of network adequacy are developed by Aetna's National Quality Management Policy Team, which is the department involved in implementation and oversight of these policies, in collaboration with Aetna's Network and Provider Data Services.

(b) ***Explanation of the evidentiary standards considered or relied upon in designing the NQTL***: The evidentiary standards and sources relied upon in designing this NQTL are the NCQA QI and NCQA MBHO QI. These guidelines provide requirements for a plan's quality improvement committee's composition and responsibilities. NCQA QI requires, at minimum, one M/S and one MH/SUD physician involved in the committee. Additionally, the MBHO QI guidelines require substantial involvement of a designated behavioral health care practitioner in the QM program and specify that the committee is responsible for recommending policy decisions, analyzing and

evaluating results of QM activities, ensuring practitioner participation in the quality management program, identifying needed actions, and ensuring follow-up as needed.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: The two factors referenced herein provide the basis for the design of Aetna's network adequacy standards and procedures. Seeking to meet the health care needs of members, by working to provide members with timely access to a sufficient number of M/S and MH/SUD in-network providers for covered services, is a basis and rationale underlying Aetna's standards and procedures relating to network adequacy, while the operation of the NQOC and related groups explains the basis and composition of the staff that deliberates and makes decisions on the design of the network adequacy standards and procedures. These two factors are complementary and are weighted equally.

Step 3, Part 2. Application of the NQTL – How Factors are Used [45 CFR 146.137(c)(3)]

Network adequacy encompasses the components of (a) network availability and (b) network accessibility, as well as additional components and processes through which the network is evaluated for adequacy, addressed in subsection (c). Each of the factors set forth herein is used to evaluate the adequacy of Aetna provider networks.

(a) Factors for network availability

- **Number of practitioners:** Aetna measures the number of practitioners as a ratio to the number of members.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in network, as numerical standards are evaluated for both M/S and MH/SUD providers. The specific ratios employed by Aetna are specific to the type of practitioner and are measured for high-volume and high-impact specialists for both M/S and MH/SUD, as well as other MH/SUD provider types and M/S primary care physicians.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and sources upon which this factor is based are applicable state law and NCQA NET 1: Availability of Practitioners and NCQA MBHO QI 3: Availability of Practitioners and Providers, which are implemented through Aetna's policy QM 10: Practitioner and Provider Availability: Network

Composition and Contracting Plan. The standard relied upon when applying this factor is specific to each type of practitioner. For both M/S and MH/SUD, Aetna identifies a high-volume practitioner type and a high-impact practitioner type to measure. High-volume specialists are a type of specialist who treat a significant portion of the membership. The M/S high-volume specialist type is obstetrics and gynecology, and the MH/SUD high-volume specialist type is masters-prepared therapists. High-impact specialists are a type of specialist who treat specific conditions that have serious consequences for the member and require significant resources. For high-impact specialists, oncology is selected for M/S, and psychiatry is selected for MH/SUD. Aetna also analyzes the availability of additional M/S and MH/SUD provider types. Appendix K sets forth the specific numeric availability standards applicable to each provider type.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: As a variation in the applicability of this factor, Aetna notes that while it measures both M/S and MH/SUD providers generally, with respect to facilities, Aetna does not specifically promulgate numeric availability standards for M/S facilities. Aetna does specifically measure and promulgate numeric availability standards for MH/SUD facilities as referenced in the charts in Appendix K. This serves as an additional check and ability to verify and promote network adequacy as it applies to MH/SUD facilities.

- **Geographic distribution of practitioners:** Aetna measures the distance to a practitioner's office from the member's home. This is calculated for different provider types, with different standards based on population density (urban, suburban, rural).

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in network, as geographic standards are evaluated for both M/S and MH/SUD providers. The distance standards employed by Aetna are specific to the type of practitioner and are measured for high-volume and high-impact specialists for both M/S and MH/SUD, as well as other MH/SUD provider types and M/S primary care physicians.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and sources upon which this factor is based are applicable state law and NCQA NET 1: Availability of Practitioners and NCQA MBHO QI 3: Availability of Practitioners and Providers, which are implemented through Aetna Policy QM 10: Practitioner and Provider Availability: Network Composition and Contracting Plan. The standard that is relied upon when applying this factor is specific to population density, with separate metrics established by urban, suburban, and rural ZIP codes, and is specific to the type of practitioner. For

both M/S and MH/SUD, Aetna identifies a high-volume practitioner type and a high-impact practitioner type to measure (the same provider types noted above). Aetna also analyzes the availability of additional M/S and MH/SUD provider types. Appendix K sets forth the specific geographic availability standards applicable to each provider type.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: As a variation in the applicability of this factor, Aetna notes that while it measures both M/S and MH/SUD providers generally, with respect to facilities, Aetna does not specifically promulgate geographic availability standards for M/S facilities. Aetna does specifically measure and promulgate geographic availability standards for MH/SUD facilities as referenced in the chart in Appendix K. This serves as an additional check and ability to verify and promote network adequacy as it applies to MH/SUD facilities.

Relationship, ordering, and weighting of multiple factors: With respect to the application of network availability, these factors are weighted equally. Neither factor is weighted more heavily than the other. Both factors contribute to the assessment of network availability, accounting for both the number of network providers available to care for members through the numeric standards, and the location of those network providers in relation to the membership through the geographic standards. As further discussed in (c) network adequacy, both factors are considered in assessing network adequacy and developing improvement plans as appropriate.

(b) Factors for network accessibility

- **Appointment waiting time** means the length of time between a member's request for an appointment and when the practitioner can see them.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in-network as appointment waiting time is evaluated for both M/S and MH/SUD providers. Aetna maintains standards pertaining to the length of time between a member's request for an appointment and when the practitioner can see the member. This is measured by provider type and type of service required (routine, urgent/emergent, after hours).

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and sources upon which this factor is based are applicable state law, and NCQA NET 2: Accessibility of Services, NCQA MBHO QI 4: Accessibility of Services, and CMS appointment timeliness standards, which are implemented through Aetna policy QM 07: Member Access to Practitioner and

Member Services Policy. The evidentiary standard that is relied upon when applying this factor is specific to the type of provider and type of appointment. Aetna establishes and measures standards for emergency and urgently needed services, routine office visits, and after-hours availability for both M/S and MH/SUD providers. For both M/S and MH/SUD, Aetna identifies a high-volume practitioner type and a high-impact practitioner type to measure (the same provider types noted above). Aetna also analyzes the availability of additional M/S and MH/SUD provider types. Specific to M/S providers, Aetna establishes standards for primary care preventive visits. Specific to MH/SUD providers, Aetna establishes standards for initial and follow-up routine mental health care, as well as services that are non-emergency/non-urgent, but require medical attention, as these are NCQA- and CMS-required metrics. Appendix K sets forth the specific accessibility standards for each provider type.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from the factor of appointment waiting time, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits. Both M/S and MH/SUD participating practitioners are expected to see patients in a timely manner, and Aetna establishes and measures timeframe standards based on the provider type and appointment type for both M/S and MH/SUD. Although there are differences in the M/S and MH/SUD standards based on the type of service and provider type, there are no deviations from the factor of appointment waiting time as it applies to MH/SUD as compared to M/S benefits.

(c) Factors for network adequacy

- **Review of accessibility and availability data:** Aetna analyzes the factors listed above in subparts (a) network availability and (b) network accessibility in the annual network adequacy analysis.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits delivered in-network, as data points relating to Aetna's accessibility and availability analyses are collected, analyzed, and trended to evaluate network adequacy.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and sources for this factor include NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network, NCQA MBHO QI 3: Availability of Practitioners and Providers, and QI 4: Accessibility of

Services, which are implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure. As set forth above, the evidentiary standard that is relied upon when applying this factor is the minimum standard for each availability and accessibility metric. These metrics are specific to the type of practitioner, and geographic metrics are specific to the population density of the ZIP code. Data points relating to Aetna's accessibility and availability analyses are collected, analyzed, and trended to evaluate network adequacy. Aetna's Member Experience Workgroups use this data to analyze barriers and plan interventions to improve the network. The M/S Member Experience Workgroup includes representation from the various network services departments at the plan level, members of the Accreditation Governance team, senior managers, lead directors and executive directors from Network Management, as well as representatives from contract negotiations. Similarly, the MH/SUD Member Experience Workgroup is comprised of staff from clinical operations, medical policy, provider services, member services, network, market compliance, product development, digital experience, and reporting teams. The Behavioral Health Quality Management team also leads monthly BH Member Experience and BH QM/Network collaboration meetings to discuss network adequacy barriers, opportunities for improvement, and interventions in response to a review of the data presented. Both the M/S and MH/SUD network interventions are reviewed annually for effectiveness, and findings are presented to the NQOC.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Assessment of member complaints related to network adequacy:** Aetna reviews member complaints for trends, which are shared with Network Strategy and Provider Experience to develop action plans to improve the provider network.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all in-network M/S and MH/SUD benefits as member complaints are evaluated for both M/S and MH/SUD benefits. As part of Aetna's processes for evaluating network adequacy, member complaints related to the provider network are monitored across all benefits and providers and are used to understand member needs and preferences.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and source for this factor include NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network, NCQA

MBHO QI 3: Availability of Practitioners and Providers, QI 4: Accessibility of Services, and QI 5: Member Experience (pertaining to network adequacy), which are implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure. The evidentiary standard relied upon when applying this factor is 0.01 complaints per 1,000 member months and a volume of five or more in the calendar year to trigger an additional qualitative review by the Network and QM teams, as required by QM 87, and adopted by the NQOC. If the complaints exceed this benchmark, Aetna conducts a qualitative analysis to examine the underlying reason for the results, including processes that may present barriers to improvement. However, all member complaints are reviewed individually by the Complaints and Appeals Department. Aetna's Member Experience Workgroups use the complaints data to analyze barriers and plan interventions to improve the network in accordance with the process set forth above in the preceding factor.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Assessment of member satisfaction survey:** Aetna evaluates the member experience using the provider network through member experience surveys.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all in-network M/S and MH/SUD benefits as member satisfaction is surveyed for both M/S and MH/SUD benefits. The member satisfaction survey is administered by an independent research firm contracted by Aetna to assess member satisfaction, including network adequacy topics of obtaining urgent and non-urgent care when needed, scheduling follow-up appointments, scheduling appointments at convenient locations, and finding providers that meet member needs and preferences.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and sources for this factor include NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network, NCQA MBHO QI 3: Availability of Practitioners and Providers, QI 4: Accessibility of Services, and QI 5: Member Experience (pertaining to network adequacy), which is implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure. As required by QM 87, Aetna includes evaluation of member satisfaction survey results in its overall analysis of network adequacy. Aetna's Member Experience Workgroups use the survey results to analyze barriers, and prioritize interventions to improve the provider network, as described above.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

- **Assessment of utilization of out-of-network services:** Aetna analyzes requests for out-of-network services using member utilization data.

(a) ***How the factor is used to determine which benefits are subject to the NQTL***: This factor applies equally to all M/S and MH/SUD benefits as out-of-network requests are evaluated for both M/S and MH/SUD providers. Out-of-network requests are reviewed for year-over-year trends as part of Aetna's evaluation to determine whether there are unmet needs in certain geographic areas or provider types.

(b) ***Explanation of the evidentiary standards considered or relied upon in applying the NQTL***: The evidentiary standards and sources for this factor include NCQA NET 3, Element A, Assessment of Member Experience Accessing the Network, and NCQA MBHO QI 5, Member Experience (pertaining to network adequacy), which are implemented through Aetna's policy QM 87: Assessment of Network Adequacy Policy & Procedure. These guidelines require an annual analysis of requests for and utilization of out-of-network services as a way to monitor member experience with the network, and through a qualitative and quantitative analysis, to identify possible causes of out-of-network requests and utilization, and to identify opportunities to improve network adequacy. Out-of-network requests are reported at the product line level per thousand members. The rate per thousand members is calculated as: [(# of out-of-network requests)/1,000 members] (membership/1,000). Aetna's Member Experience Workgroups use the out-of-network utilization data to analyze barriers and plan interventions to improve the network, as described above.

(c) ***If the factor depends on specific decisions made in the administration of benefits***: This factor does not depend on specific decisions made in the administration of benefits.

(d) ***Deviations or variations from a factor***: There are no deviations or variations from this factor, its applicability, or its definition as it applies to MH/SUD as compared to M/S benefits.

Relationship, ordering, and weighting of multiple factors: With respect to the application of network adequacy, all factors are weighted equally. Each factor contributes to the overall analysis of network adequacy in its totality and the development of action plans to improve the network. Each factor is used to identify and prioritize opportunities for improving the provider network.

Step 4: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

*This Step 4 demonstrates that, under the terms of the plan, **as written**, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits. Accordingly, this Step 4 is addressed in two Parts: **(1)** design and **(2)** application. Within each such discussion, this Step 4 addresses **(a)** documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification, **(b)** in each classification in which the NQTL applies to MH/SUD benefits, a comparison of how the NQTL, as written, is designed and applied to MH/SUD benefits, including the specific provisions of written materials used to design or apply the NQTL, **(c)** documentation of how the factors are comparably applied, as written, to MH/SUD and M/S benefits, and **(d)** as applicable, an explanation of any deviations or variations in the application of a factor.*

Step 4, Part 1. Design of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, network adequacy applies to all M/S and MH/SUD benefits delivered in network, including the following benefit classifications: in-network inpatient; in-network outpatient, both office and all other; and emergency. As noted in Step 2, Part 1, the factors relied upon in the design of Aetna's network adequacy standards and procedures are: 1) meeting the health care needs of members and 2) operation of the NQOC and related groups. Seeking to meet the health care needs of members, by working to provide members with timely access to a sufficient number of M/S and MH/SUD in-network providers for covered services, is a basis and rationale underlying Aetna's standards and procedures relating to network adequacy, and the operation of the NQOC and related groups explains the basis and composition of the staff that deliberates and makes decisions on the design of the network adequacy standards and procedures. These design factors do not distinguish between, and are equally applied to, both M/S and MH/SUD benefits. In other words, both factors apply equally to both benefit types.

Meeting the health care needs of members, as defined in Step 2, Part 1, above, is a general design factor that does not distinguish between, and is equally applied to, both M/S and MH/SUD benefits. As explained above, the evaluation of network adequacy, including accessibility and availability of M/S and MH/SUD network providers, is part of Aetna's QM program. The QM program influences more than network adequacy, but specific to network adequacy, availability, and accessibility, the QM program charges the NQOC with establishing standards for network adequacy for meeting the health care needs of members and monitoring compliance with M/S and

MH/SUD network adequacy standards. QM and Network teams work together to identify trends and gaps, to address opportunities for improvement, and to assess the effectiveness of planned interventions. The **QM Program Description** outlines the components of the QM program, including network adequacy, network availability, and network accessibility, and also details the accountability and committee structure for QM activities. The QM program operates in compliance with and is responsive to applicable requirements of plan sponsors, federal and state regulators, and appropriate accrediting bodies, including NCQA. The QM Program Description refers to the evidentiary standards of commitment to NCQA accreditation as one means of demonstrating a commitment to quality, as well as ensuring compliance with applicable state laws, which apply equally with respect to M/S and MH/SUD services. The QM Program Description provides a foundation for the QM policies discussed in Step 4, Part 2, below.

Additionally, the QM Program Description sets forth documentation relating to the NQOC and related groups that make decisions relating to the design of network adequacy standards and procedures. The QM Program Description describes the purpose of the NQOC and its role and responsibilities, which include adoption of QM policies and procedures, including the QM policies that design the metrics and assessment of network adequacy. These policies are developed by the National Quality Management Policy Team, which is the Aetna department involved in implementing and overseeing the policies in collaboration with Network Strategy and Provider Experience related to network adequacy, in conjunction with and subject to the approval of the NQOC. The NQOC is a multidisciplinary committee composed of department personnel representing both M/S and MH/SUD across several functional areas. The NQOC includes representation from Aetna's behavioral health business segment for all functions: medical directors, network management, clinical health services, customer service, and quality management. The NQOC voting member roster is included in Appendix H.

The factors of meeting the health care needs of members and the operation of the NQOC and related groups are equally applicable to both M/S and MH/SUD benefits and are not applied incomparably or more stringently to MH/SUD benefits. Similarly, there are no deviations or variations in these factors as they apply to the design of network adequacy. As written, the processes, strategies, evidentiary standards or other factors used in designing network adequacy with respect to MH/SUD benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing the NQTL with respect to M/S benefits.

Step 4, Part 2. Application of NQTL: Demonstration of Comparability and Stringency, As Written [45 CFR 146.137(c)(4)]

As noted in Step 1, network adequacy applies to all M/S and MH/SUD benefits delivered in-network, including the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient–office; 3) in-network outpatient–all other; and 4) emergency. As noted in Step 2, Part

2, network adequacy encompasses the components of (a) network availability and (b) network accessibility, as well as additional components and processes through which the network is evaluated for adequacy, addressed in subsection (c). This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in applying network adequacy to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying network adequacy to M/S benefits across the applicable benefit classifications.

The below internal written policies are predicated upon Aetna's QM program. These policies reflect the above-referenced evidentiary standards and sources of applicable state law and the NCQA Network Management guidelines. As part of Aetna's accreditation, NCQA reviews the documented processes, policies, and procedures, and determines the same are sufficient to achieve NCQA accreditation. The internal policy and procedure QM 01: Quality Management and Credentialing Policy and Procedure Development and Review Policy and Procedure applies to MH/SUD and M/S benefits and establishes a consistent process for developing and reviewing QM policies, including the departments involved in developing new policies, signature authority for QM policies and the required QM Policy Committee approval, and NQOC adoption. When state laws/regulations vary from the core requirements of QM policies, the differences are documented in a state amendment. As stated throughout this analysis, where a state has applicable requirements, Aetna follows and applies the most stringent standard as between Aetna core requirements and the state requirements. More stringent state requirements supersede QM policy requirements.

(a) Network availability

As set forth in Step 2, Part 2, factors relied upon or considered to apply network availability include: 1) number of practitioners and 2) geographic distribution of practitioners. Aetna applies the internal policy and procedure **QM 10: Practitioner and Provider Availability: Network Composition and Contracting Plan** for assessing network availability for both M/S and MH/SUD providers. This policy is discussed below, demonstrating that it is comparably applied, as written, to M/S and MH/SUD services.

QM 10 establishes a process by which practitioner and provider availability standards are set and periodically assessed by the NQOC and used to improve network adequacy. This policy defines minimum requirements for network composition and promotes compliance with applicable state and federal regulatory standards as well as applicable NCQA accreditation standards. Aetna maintains a detailed Provider Availability Standards grid as part of QM 10, which documents the standards the NQOC has adopted for both M/S and MH/SUD metrics for number and geographic distribution of providers. The Provider Availability Standards grid houses state standards, where applicable, as well as the national standards Aetna uses in absence of a state requirement. Per the policy, the scope of the availability analysis must include:

- Primary care physicians
- **High-volume M/S specialist – obstetrics/gynecologist**
- **High-impact M/S specialist – oncologist**
- Behavioral Health (MH/SUD) practitioner – psychologist
- Behavioral Health (MH/SUD) providers – inpatient, residential, and ambulatory facilities
- **High-volume MH/SUD practitioner – masters-prepared therapist**
- **High-impact MH/SUD practitioner – psychiatrist**

For both M/S and MH/SUD, the standards for provider-to-member ratios are intended to represent measurable standards for the number of each type of practitioner. For both M/S and MH/SUD, the standards for geographic availability are measured based on the members' home addresses in relation to provider office locations. The same population density definitions of urban, suburban, and rural apply to M/S and MH/SUD networks. The metrics are set for each category, and both M/S and MH/SUD require closer practitioners for urban members and allow further distances between rural members and providers.

For both M/S and MH/SUD, Aetna's core standards reflect standards applicable to both a high-impact and high-volume practitioner, as well as other practitioners. For both M/S and MH/SUD, pursuant to the policy, compliance is measured based upon the stricter of the Aetna core standard, or an applicable state requirement. While specific numeric and geographic standards may vary among provider type, as written, the factor applies to M/S and MH/SUD benefits comparably. Additionally, as set forth above, for both the numeric and geographic standards, Aetna does not expressly promulgate and measure such requirements with respect to M/S facilities, but does do so with respect to MH/SUD facilities, which serves as an additional measure to promote network adequacy as it relates to MH/SUD benefits. Aetna's analysis of the "as written" materials (QM policies and procedures) used to assess network availability shows that the factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services.

(b) Network accessibility

As set forth in Step 2, Part 2, the factor relied upon or considered to apply network accessibility is appointment waiting times. Aetna applies the internal policy and procedure **QM 07: Member Access to Practitioner and Member Services Policy** for assessing network accessibility for both M/S and MH/SUD providers. This policy is discussed below, demonstrating that it is comparably applied, as written, to M/S and MH/SUD services.

This policy, *inter alia,* defines the standards for M/S and MH/SUD practitioner appointment accessibility and establishes a mechanism for monitoring, evaluating, and managing member access to practitioners. This policy and its state amendments define minimum requirements for appointment waiting time, based upon applicable state standards as well as

applicable NCQA accreditation standards. The accessibility standards and methodology are detailed in grids attached to this P&P; standards are set for both M/S and MH/SUD practitioners:

- Primary care physician: regular or routine appointments, urgent/emergent matter, preventive care appointments, and after-hours care
- **High-volume and high-impact M/S specialist**: regular or routine appointments, urgent/emergent matter, and after-hours care
- MH/SUD practitioners (**high-volume, high-impact,** and other practitioners): regular or routine initial appointment, emergency, urgent care evaluation and treatment, non-emergency/non-urgent but requires medical attention, follow-up routine care, and after-hours care

This policy requires Aetna to notify participating providers about these access standards in the Provider and Facility Participation Criteria and Provider Manuals. These measures are monitored annually and reported to NCQA as part of Aetna's Health Plan and Managed Behavioral Health Organization accreditation.

For both M/S and MH/SUD, Aetna's core standards reflect requirements applicable to high-impact and high-volume M/S and MH/SUD practitioners, as well as various additional M/S practitioners and MH/SUD practitioners. For both M/S and MH/SUD, emergency and urgently needed services are defined as when a prudent layperson with an average knowledge of health and medicine, believe that they have medical symptoms that require immediate medical attention to: prevent loss of life (or for pregnant woman, loss of an unborn child), loss or loss of function of a limb or serious impairment to a bodily function; worsening medical symptoms of an illness, injury, severe pain, or a medical condition to prevent death or serious harm to the member or others (acute suicidality). For both M/S and MH/SUD, urgent care is defined as a condition that would likely deteriorate or pose risk of serious harm if not treated. For both M/S and MH/SUD, routine care is defined in materially the same way. (For M/S, routine care is defined as care for non-urgent conditions that, if not treated, may pose minimal risk of immediate harm. For MH/SUD, routine is a clinical situation that is sufficiently stable and does not have a negative impact on the member's condition.) For both M/S and MH/SUD, after-hours care refers to the ability of members to obtain instructions on how to receive care outside of normal business hours. For both MH/SUD and M/S, pursuant to the policy, compliance is measured based upon the stricter of the Aetna core standard or an applicable state requirement. Specific access standards vary across provider types, but generally, Aetna applies comparable network accessibility standards to MH/SUD services as to M/S services, including immediate care or referrals to appropriate emergency care, and after-hours voicemail or answering service requirements. Additionally, the standards for routine office visit for high-volume providers (ob/gyn for M/S and masters-prepared therapist for MH/SUD) and high-impact providers (oncologist for M/S, and psychiatrist for MH/SUD) provide a means of assessing comparability. As outlined in Appendix K, routine office visits are required within 10 days for MH/SUD high-impact and high-volume practitioners, and within 30 days for M/S high-impact and high-volume practitioners. The shorter appointment time standard for MH/SUD

practitioners serves as an additional measure to promote accessibility to these MH/SUD providers. Aetna's analysis of the "as written" materials used to assess network accessibility shows that the factors, evidentiary standards, and sources are applied comparably to M/S and MH/SUD services and are not more stringently applied to MH/SUD services.

(c) Network adequacy

As set forth in Step 2, Part 2, factors relied upon or considered to apply additional components and processes through which Aetna evaluates network adequacy are: 1) review of accessibility and availability data; 2) assessment of member complaints; 3) assessment of member satisfaction surveys; and 4) assessment of out-of-network utilization. Aetna applies the internal policy and procedure **QM 87: Assessment of Network Adequacy P&P** for assessing network adequacy for both M/S and MH/SUD providers. This policy is discussed below, demonstrating that it is comparably applied, as written, to M/S and MH/SUD services.

QM 87 is Aetna's policy and procedure pertaining to obtaining an overall picture of network adequacy, assessing network adequacy, identifying opportunities to improve network adequacy, and evaluating implemented activities for effectiveness. For both M/S and MH/SUD networks, Aetna's Accreditation Governance teams complete an annual quantitative and qualitative analysis by product that includes member complaints, accessibility (detailed in QM 07), availability (detailed in QM 10), out of network requests, and member experience/member satisfaction survey data. As written, for both M/S and MH/SUD, the same data sources are evaluated to undertake this analysis, except that different survey sources are used for the factor of member experience data/member satisfaction surveys. For M/S, the member experience data is obtained through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. This is a standardized survey sponsored by the Agency for Health Care Research and Quality and does not include MH/SUD. Therefore, Aetna conducts an independent Behavioral Health Member Experience Survey to gather data on members' experience obtaining care from MH/SUD providers. Although the member surveys are not on the same form, the questions gather similar information about the member experience for Aetna to use in network improvement activities.

Aside from the distinct surveys, the process for evaluating network adequacy, identifying opportunities to improve network adequacy, developing improvement activities, and evaluating the effectiveness of those activities is the same for M/S and MH/SUD services. QM 87 requires Aetna's Accreditation Governance team and Network Management to use the results of these analyses to identify and prioritize opportunities for improvement. The effectiveness of these interventions is evaluated in the following year's network availability and accessibility evaluations. The NQOC is responsible for approving the analyses and improvement activities for both M/S and MH/SUD. As written, the processes, strategies, evidentiary standards and other factors used in applying network adequacy to MH/SUD benefits are comparable to, and are applied

no more stringently than, the processes, strategies, evidentiary standards and other factors used in applying the NQTL to M/S benefits in the applicable benefit classifications.

Step 5: Demonstration of Comparability and Stringency, In Operation [45 CFR 146.137(c)(5)]

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

The quantitative data presented in this analysis is based on Aetna Life Insurance Company (ALIC) business, which represents approximately 74% of the total Virginia business. The NQTL processes, strategies, evidentiary standards, and other factors described herein are applied consistently across the relevant Virginia business. As a result, Aetna believes the ALIC data is representative of the operational application of the NQTL and provides a reliable basis for assessing compliance with MHPAEA's comparative analysis requirements and for supporting the findings and conclusions presented in this report.

As noted in Step 1, network adequacy applies to all M/S and MH/SUD benefits delivered in-network, including the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient–office; 3) in-network outpatient–all other; and 4) emergency. In accordance with Aetna's policy QM 87: Assessment of Network Adequacy, in order to assess network adequacy, identify opportunities to improve network adequacy, and to implement and evaluate implemented activities for effectiveness, Aetna will perform an annual qualitative and quantitative analysis, by product, for the M/S network and MH/SUD network. This analysis includes data related to the factors identified in Step 2. This section demonstrates that, in operation, across all applicable benefits classifications, the processes, strategies, evidentiary standards, and other factors used in designing and applying network adequacy with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying network adequacy with respect to M/S benefits.

(a) Network availability

- **Number of practitioners** is a point-in-time measurement, which means the practitioner and membership totals are used for the analysis from a certain point in the year. The total number of participating providers, by type, are counted for each state and divided by the total membership

count for each state, according to the ratio standard for each type. For certain provider types, only a subset of the membership is counted. For M/S providers, the membership measured for pediatricians is age 17 and younger, and for ob/gyns, the membership used is female members ages 13 and older. For MH/SUD providers, the membership for psychiatrists treating children is based on members ages 17 and younger.

- The M/S PPO/EPO network met or exceeded the standards established for the practitioner-to-member ratio standards in the state of Virginia. The practitioner types measured are: General Practice and Family Practice, Internal Medicine Practitioner, Pediatrics, Obstetricians/Gynecologist (high-volume specialist), and Oncology (high-impact specialist).
- The MH/SUD PPO/EPO network met or exceeded the standards established for the practitioner-to-member ratio standards in the state of Virginia. The practitioner types measured are: Psychiatrist (high-impact practitioner), Psychologist, Masters-Prepared Therapist (high-volume practitioner), and Psychiatrist Treating Children.
- The MH/SUD PPO/EPO network met or exceeded the standards established for the facility-to-member ratio standards in the state of Virginia. The facility types measured are: behavioral health ambulatory, behavioral health inpatient, and behavioral health residential treatment.

- **Geographic distribution of practitioners** is a point-in-time measurement, which means the practitioner and membership data used for the analysis are from a certain point in the year. Geo-availability software is used to determine the minimum distance to each provider type using the provider office locations and the member home addresses. Membership is separated into population density areas, defined below. The compliance rate is calculated as the percentage of members within a defined population density area who live within the travel standard for each provider type, as compared to the total membership in that population density area.
  - The population density areas are urban, suburban, and rural by ZIP code, determined by data from the US Census Bureau.
    - Urban population density is greater than 3,000 persons per square mile.
    - Suburban population density is between 1,000 and 3,000 persons per square mile.
    - Rural population density is less than 1,000 persons per square mile.

The charts below show the percentage of members with providers available within the standard for M/S and MH/SUD high-impact and high-volume practitioners. These results are reflective for the state of Virginia, for calendar year 2025.

2025 High-Volume Virginia Provider Geographic Availability (PPO/EPO Network)		
	M/S - Ob/Gyn	**MH/SUD - Masters-Prepared Therapist**

Urban	99.7%	100%
Suburban	98.6%	98.5%
Rural	100%	100%
Virginia/total	**99.4%**	**99.5%**

2025 High-Impact Virginia Provider Geographic Availability (PPO/EPO Network)		
	M/S - Oncologist	**MH/SUD - Psychiatrist**
Urban	98.8%	99.9%
Suburban	98.6%	98.3%
Rural	100%	100%
Virginia total	**99.1%**	**99.4%**

As described throughout this analysis, Aetna also measures geographic availability for additional provider types pursuant to Aetna's Policy QM 10. The geographic availability results for those additional provider types are in the next charts.

2025 MH/SUD Virginia Provider Geographic Availability (PPO/EPO Network)					
	Psychologist	**Psychiatrist Treating Children**	**BH Ambulatory Facilities**	**BH Inpatient Facilities**	**BH Residential Treatment Facilities**
Urban	99.9%	99.8%	99.7%	94.7%	95%
Suburban	95.6%	98.4%	93.2%	84.2%	84.2%
Rural	99.9%	100%	97.8%	90.6%	99.9%
Virginia/Total	**98.5%**	**99.4%**	**96.9%**	**89.8%**	**93%**

2025 M/S Virginia Primary Care Provider Geographic Availability (PPO/EPO Network)			
	Internal Medicine	**General and Family Practice**	**Pediatrics**
Urban	99.9%	99.9%	99.9%
Suburban	100%	100%	99.9%
Rural	100%	100%	100%
Virginia/Total	**99.96%**	**99.96%**	**99.99%**

(b) Network accessibility

- **Appointment waiting time** results are measured as a point-in-time in 2025 using survey responses. For M/S, PCP appointment waiting time data is from the member CAHPS survey questions pertaining to accessibility, which is analyzed in conjunction with the results of member complaints related to access. For M/S, Aetna monitors appointment accessibility at the state level, because the Health Plan NCQA surveys are assessed at the Accreditable Entity level. For MH/SUD, appointment accessibility is based on provider responses to the Aetna Behavioral Health Provider Experience Survey and is monitored only at the national level.

Aetna captures data from these sources of information to measure provider compliance with the appointment standards based upon the provider types and appointment types referenced in Appendix K. As noted, results are only reported at the national level, for all products, inclusive of Virginia, and are not available at the individual state level. Therefore, we are relying on the national comparative analysis for appointment wait times results. For comparison, the national analysis shows variation among results as between MH/SUD high-impact (psychiatrist) and high-volume (masters-prepared therapist) specialists, and M/S high-impact (oncologist) and high-volume (ob/gyn) specialists for the relevant appointment types which include emergency, urgently needed services and after-hours care, as well as regular and routine appointments. The national data reflects both MH/SUD and M/S practitioners meeting the applicable standards in some areas, but not in others. There is some difficulty in comparing results based on state and national reporting levels, but overall and on balance, the results of this analysis demonstrate comparable in-operation results as to network accessibility for MH/SUD benefits and M/S benefits.

  - MH/SUD practitioner data reflects a higher percentage of compliance with the standards for initial, routine and follow-up care as compared to M/S practitioner compliance with the standard for regular and routine care appointments.
  - MH/SUD practitioner data reflects a lower percentage of compliance with standards for emergency and urgently needed services as compared to M/S practitioner compliance with the standards for emergency and urgently needed services.

(c) Network adequacy

- **Assessment of member complaints** related to network adequacy is based on complaints members filed, either verbally or in writing, about network adequacy topics. The 2025 network adequacy member complaint and appeal reports were compiled by the QM Reporting Department. Complaint data is measured retrospectively; therefore the 2025 analysis uses data from January – December 2024. Member satisfaction related to network adequacy is assessed through the evaluation of complaint data. Specifically, the complaint and appeal tracking system (CATS) categories assessed relate to network adequacy as well as accessibility and availability.

Results are reported as a per 1,000-member month rate. Any health plan complaints at or in excess of 0.01 per thousand member months with a volume of five or more will be further assessed. Complaints per 1,000 member months are determined according to the following formula: actual number of complaints received divided by (sum of monthly membership for 12 months)/1,000.

  - A complaint is any oral or written expression of dissatisfaction/concern, other than an appeal, by a member or a member's authorized representative regarding services provided by Aetna, a health care professional, or a vendor.
  - The member months reflect the number of individuals covered under the plan each month, calculated by the number of members multiplied by the number of months they were covered during the year.

For the Virginia MH/SUD and M/S PPO/EPO networks, there were 0 complaints related to network adequacy, and these results were below the threshold for additional review.

Below are the complaint types for MH/SUD and corresponding M/S complaints.

Complaint Type	M/S	MH/SUD
Access to provider	0	0
Access to care	0	0
Network adequacy	0	0
Appointment availability	0	0
Provider left the network	0	0

- **Assessment of member satisfaction survey** is based on the 2025 CAHPS Survey for M/S networks and the 2025 Behavioral Health Member Experience Survey for MH/SUD networks. Each of these member satisfaction surveys includes question(s) to assess member satisfaction with the health plan's network, among other things.

The CAHPS Satisfaction Surveys are conducted annually, and results are analyzed for all applicable measures. Responses to the network adequacy question are analyzed in conjunction

with the results of member complaints related to network adequacy. The below shows the network adequacy question and the state of Virginia percentage of favorable responses.

2025 Virginia Commercial PPO CAHPS – M/S Network Related Question	
Question	**Percentage of Favorable Responses**
In the last 12 months, how often were you able to find the right care, at the right time, within a reasonable distance?	84.89%

For MH/SUD, the 2025 Member Experience Survey was developed via collaboration among several members of the BH QM team, with input from other BH stakeholder teams as needed. The survey includes 6 multiple-choice questions pertaining to satisfaction with the provider network. Results are only reported at the national level, for all products, and are not available at the Virginia state level.

2025 Aetna Behavioral Health National Member Survey Network Related Questions	
Question	**Percentage of Favorable Responses**
Please rate your behavioral health care provider(s) on the following item:	
Speaking the language that you feel comfortable with	97.4%
Understanding your culture/ethnicity/race/religion	94.6%
Please rate the following items for the behavioral health care and services you received (in person, by phone or by video):	
Scheduling a behavioral health appointment at a convenient location	85.3%
Getting help for an urgent behavioral health need	79.5%
Getting help for a non-urgent behavioral health need	84.6%
Scheduling a follow-up appointment for a behavioral health need	91.0%

- **Review of accessibility and availability data:** Aetna analyzed the factors listed above in (a) network availability and (b) network accessibility in the annual national network adequacy analysis, the results of which are listed above.

- **Assessment of utilization of out-of-network services** is measured at the Virginia state level, for the time period of 7/1/25-6/30/26. Based on an analysis of utilization management

(precertification, concurrent review, and retrospective review) during this time period, the following activity was found:

- The data is based on precertification, concurrent review, and retrospective review requests for out-of-network services in the 7/1/25-6/30/26 timeframe.
- The rate per 1,000 members is calculated by the number of requests divided by the membership and multiplied by 1,000. The membership is reflective of the July 2025-June 2026 timeframe.
- The approval rate is the number of approved requests divided by the total number of requests.

7/1/25-6/30/26 Virginia Out of Network Requests PPO/EPO network (ALIC)		
	M/S	**MH/SUD**
Inpatient Rate per 1,000 Members	0.49	0.49
Outpatient Rate per 1,000 Members	1.47	0.87
Overall Approval Rate	**60%**	**76%**

Aetna conducted a detailed review of this data. This review identified which levels of care had the highest rates of out-of-network requests. For both M/S and MH/SUD, the levels of care with the highest rates were related to outpatient care. Overall, Aetna approves MH/SUD out-of-network requests for MH/SUD benefits for the service levels identified at a higher rate of 76%, as compared to the 60% approval rating for M/S out-of-network requests. The higher approval rate for MH/SUD out-of-network requests reflects Aetna's proactive approach to ensuring members have meaningful access to behavioral health services when in-network options are unavailable.

Summary

This evaluation of network adequacy, availability, and accessibility demonstrates that the processes, strategies, evidentiary standards and other factors used to design and apply the NQTL are applied comparably to M/S and MH/SUD providers and benefits. The framework and process for performing the evaluation and identifying, conducting and measuring improvement activities, in operation, is conducted in a comparable manner for M/S and MH/SUD. The factors are measured comparably, and all contribute to Aetna's annual initiatives to improve network adequacy.

As to network availability, both M/S and MH/SUD network availability numeric goals were met in the state of Virginia, meaning that the established ratios for the number of practitioners per member were met at the state level. Aetna maintains an open panel for new M/S and MH/SUD providers to request participation in the network, even when the standard is met in the state of Virginia. Regarding geographic availability, the geographic availability analysis results for high volume providers (ob/gyn for M/S, and masters-prepared therapist for MH/SUD) and high impact providers (oncologist for M/S, and psychiatrist for MH/SUD) provide a means to measure

comparability. The overall Virginia totals show similar and comparable results for MH/SUD and M/S high volume (99.4.7% for M/S, and 99.5% for MH/SUD) and high-impact providers (99.1% for M/S and 99.4% for MH/SUD). Additionally, as noted above, Aetna core standards include measurement of numeric and geographic standards for MH/SUD facilities, while Aetna does not expressly measure such requirements with respect to M/S facilities. The results of the evaluation of these metrics for MH/SUD facilities demonstrate that Virginia did not meet its standards in all instances. However, the fact that Aetna evaluates these measures for MH/SUD facilities in and of itself demonstrates a comparable and not more stringent application of network adequacy, because the measurement of these standards serves as an additional measure to promote network adequacy as it relates to MH/SUD facilities (which are not measured for M/S facilities).

As to network accessibility, appointment accessibility was measured for both M/S and MH/SUD practitioners to monitor available appointments for various types of care. As noted, results are only reported at the national level, for all products, inclusive of Virginia, and are not available at the individual state level. Therefore, we are relying on the national comparative analysis for appointment wait times results. The national analysis revealed some variation among results as between M/S benefits and MH/SUD benefits for various types of appointments (e.g., MH/SUD practitioners reported appointment availability that met the standard for routine initial and follow-up care but did not meet the standard for emergency and urgently needed services). Overall, the results of this analysis demonstrate comparable in-operation results as to network accessibility for MH/SUD benefits and M/S benefits. The national results reflect that a higher percentage of M/S high volume and high impact practitioners met standards for emergent/urgent care, but a higher percentage of MH/SUD practitioners offered appointments that met the standard for non-urgent, non-emergent, initial, routine, and follow-up care. With respect to MH/SUD after hours care, Aetna's after-hours availability standard for 2025 cannot be determined due to a survey fielding error. As set forth below in Step 6, all the network accessibility and network availability data, as well as the other network adequacy data metrics collected identifying these trends, allows Aetna to examine what actions can be taken to improve member access to care and network adequacy as part of its annual analysis. This annual analysis is a component of Aetna's QM Program, which the NQOC reviews and evaluates for effectiveness.

In the state of Virginia for both M/S and MH/SUD, there were zero member complaints regarding access to providers, access to care, and network availability. For member survey data, each of the member satisfaction surveys includes question(s) to assess member satisfaction with the health plan's network, among other things. Results are only reported at the national level for the behavioral health member satisfaction survey and cannot be compared to the M/S results for the state of Virginia. Therefore, we are relying on the national comparative analysis to assess overall satisfaction with network adequacy and accessibility. The national results reflect comparable results between MH/SUD and M/S. This national evaluation demonstrates comparable in-operation results as to these network adequacy metrics for MH/SUD and M/S benefits.

Moreover, deeper qualitative analysis of the complaint and survey data by the QM team allow for action planning to address potential member concerns.

The assessment of Virginia out-of-network utilization shows a higher out-of-network request rate for inpatient and outpatient services for M/S benefits than for MH/SUD benefits. However, the MH/SUD approval rate for out-of-network services was higher for MH/SUD services than for M/S services, at 76% compared to 60%. While the higher percentage of authorization indicates that there is a process in place to accommodate members, the Network teams continue to review the details by level of care to better understand the reasons for members' out-of-network utilization in order to evaluate network fortification actions.

All of the factors discussed herein are evaluated to provide a total picture of network availability, accessibility and adequacy. Taken together and in the aggregate, this analysis demonstrates that in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying network adequacy to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying network adequacy to M/S benefits. Moreover, all of these outcome data elements are used to identify and prioritize network adequacy improvement actions. Aetna's QM team facilitates Member Experience Workgroups for both M/S and MH/SUD networks, each comprised of individuals in similar roles with expertise in either M/S or MH/SUD provider networks. These workgroups identify and prioritize initiatives to improve network adequacy, conduct barrier analyses, and develop actionable steps. These plans, detailed below in Step 6, are presented to the NQOC each year, as well as an evaluation of the prior year's initiatives and their effectiveness.

Step 6: Findings and Conclusions [45 CFR 146.137(c)(6)]

This Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: ***(a)*** *any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions;* ***(b)*** *if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis;* ***(c)*** *the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and* ***(d)*** *to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.*

As demonstrated in Step 1, network adequacy refers to the ability of a health plan to provide members with timely access to a sufficient number of in-network providers, both M/S and MH/SUD. Aetna works to maintain sufficient numbers and types of M/S and MH/SUD providers in its network and implements standards for access to appointments for covered M/S and MH/SUD services. Aetna monitors how effectively its network meets the needs and preferences of its members through an evaluation of network availability, network accessibility, and the additional procedures and measures set forth herein. As further demonstrated in Step 1, network adequacy applies to all M/S and MH/SUD benefits delivered in-network including the following benefit classifications: 1) in-network inpatient; 2) in-network outpatient, both office and all other; and 3) emergency services. Step 2 identified the factors used to develop and monitor network adequacy, including the components of (a) network availability; (b) network accessibility; and (c) additional components and processes through which the network is evaluated for adequacy. Step 3 explained the evidentiary standards and sources for those factors, and how those standards are applied to M/S and MH/SUD providers. Step 4 then explained how those factors are applied, in writing, to M/S and MH/SUD network providers and concluded that there are no written differences in that application that results in any MH/SUD providers or benefits being treated more stringently than, or incomparably to, M/S providers or benefits. Finally, Step 5 demonstrated that, in operation, M/S and MH/SUD provider networks are monitored for adequacy, availability, and accessibility in a comparable and no more stringent manner.

Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR 146.136(c)(4). As demonstrated in Steps 1-4, Aetna applies the same factors to establish network adequacy standards and processes for M/S and MH/SUD providers, and to evaluate the same. As noted in Step 2, Part 1, the factors relied upon in the design of Aetna's network adequacy standards and procedures are: 1) meeting the health care needs of members and 2) operation of the NQOC and related groups. Efforts to meet the health care needs of members, by working to provide members with timely access to a sufficient number of M/S and MH/SUD in-network providers for covered services, is a basis and rationale underlying Aetna's standards and procedures relating to network adequacy, while the operation of the NQOC and related groups explains the basis and composition of the staff that deliberates and makes decisions on the design of network adequacy standards and procedures. As discussed above, the same written policies apply to both M/S and MH/SUD benefits, and the same body, the NQOC, adopts the policies that design the metrics and assessment of network adequacy. The NQOC is a multidisciplinary committee that includes both M/S and MH/SUD representation.

In the application of network adequacy, with respect to network availability and accessibility, Aetna applies the same policies and procedures in order to assess network availability and accessibility for both M/S and MH/SUD providers. Aetna further applies the same policy and procedure to assess network adequacy for both M/S and MH/SUD providers. For both M/S and MH/SUD networks, Aetna's Accreditation Governance teams complete a quantitative and qualitative analysis by product that includes member complaints, accessibility, availability, out of network requests, and member experience/member satisfaction survey data. Aside from using distinct member surveys for M/S and MH/SUD (which gather similar information about member experience), the process for evaluating network adequacy, identifying opportunities to improve network adequacy, developing improvement activities, and evaluating the effectiveness of those activities is the same for M/S and MH/SUD services. Additionally, as to both the M/S and MH/SUD networks, the written policy requires Aetna's Accreditation Governance team and Network Management to use the results of these analyses to identify and prioritize opportunities for improvement.

As demonstrated in Step 5, in order to assess network adequacy, identify opportunities to improve network adequacy, and to implement and evaluate implemented activities for effectiveness, Aetna will perform an annual qualitative and quantitative analysis for the M/S network and MH/SUD network, including data relating to the factors identified herein. The framework and process for performing the evaluation, and identifying, conducting and measuring improvement activities, in operation, is conducted in a comparable manner for M/S and MH/SUD. The factors are measured comparably, and all contribute to Aetna's annual initiatives to improve network adequacy. As demonstrated in Step 5, there are instances where the Virginia network adequacy evaluation provides information about metrics in specific locales that were not met for MH/SUD facility providers. As previously discussed, Aetna core standards include measurement of numeric and geographic standards for MH/SUD facilities, while Aetna does not expressly

measure such requirements with respect to M/S facilities. However, the fact that Aetna evaluates these measures for MH/SUD facilities in and of itself demonstrates a comparable and not more stringent application of network adequacy, because the measurement of these standards serves as an additional measure to promote network adequacy as it relates to MH/SUD facilities (which are not measured for M/S facilities). Taken together and in the aggregate, this analysis demonstrates that in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying network adequacy to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying network adequacy to M/S benefits. Aetna evaluates information from member complaints, member satisfaction surveys and out-of-network utilization rates that can provide valuable insight into ways to improve Aetna's MH/SUD and M/S networks. This information is evaluated by Aetna's Member Experience Workgroups, which include M/S and MH/SUD representation, and results in intervention activity each year. Interventions are prioritized based on the results of the factors used to evaluate network availability and accessibility. The planned interventions are presented to the NQOC and evaluated each year through the reassessment of network adequacy.

The M/S initiative based on the 2025 adequacy analysis is related to access to care. Based on this year's analysis of the noted data sources, Aetna will continue to work on access to care as an opportunity to enhance the membership's timely access to various provider types and facilities. Improvement activities include topics related to expanding access to telemedicine, including primary care telemedicine. Aetna sent email and direct mail to eligible members about how to access telemedicine, including services members may not know are available virtually. Aetna also conducted training for customer service staff regarding telemedicine and how to verify a member's telemedicine benefits. The MH/SUD initiative based on the 2025 adequacy analysis is to increase numeric and geographic availability of MH/SUD practitioners and providers (both in-person and telemedicine) by growing the network, and the action plans include continuing existing actions as well as planning new actions. These action plans include continued focus on telemedicine. Aetna has added 30+ new national virtual MH/SUD provider groups to Aetna's Mental Health Care Virtual Care website, which includes multiple provider types such as psychiatrists, psychologists, licensed clinical social workers, licensed professional counselors, and other independently licensed practitioners. Similar telehealth expansion in the Virginia network reflects the addition of over 5,300 BH providers between calendar year 2025 through July 2026. Aetna continues to review member telehealth utilization to identify opportunities to increase virtual appointment availability throughout the network. Additionally, the 2025 MH/SUD network accessibility initiatives target improving timeliness of emergency/urgent and after-hours MH/SUD care by increasing the availability of network providers, ensuring practitioners are aware of the timeliness standards, and collaborating with Aetna Network Management's review of the provider experience survey to enhance provider service. To increase the number of practitioners in the network, Aetna maintains an open panel for new MH/SUD providers to request participation in the network, even when the standard is met. The Network actions to improve provider availability also include:

- Multi-faceted provider recruitment strategy which identifies prospective providers through several different channels including member and plan sponsor feedback/referrals, as well as competitive network and out-of-network utilization data.
- Provider reimbursement rates are reviewed at least annually and updated to promote local market competitiveness and alignment with CMS rates.
- Providing network staff independence to offer premium rates for high demand provider types and groups/facilities in high need geographic areas.
- Continue to review and update reimbursement rates in target regions to promote local market competitiveness.
- Continue large scale recruitment efforts targeting providers with higher volume out-of-network utilization.
- Continue optimizing recruitment and onboarding process to highlight the benefits of participating in our network.
- Collaborate with provider data and contract audit teams to ensure all provider demographic and contract updates are processed accurately and timely, ensuring a positive provider experience.

These initiatives led to the addition of 80,029 MH/SUD practitioners and 4,758 MH/SUD facility locations to the network in 2024, and 14,374 MH/SUD practitioners and 524 MH/SUD facility locations added during Q1 2025.

From this information, Aetna concludes that, both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply network adequacy with respect to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards and other factors used to design and apply network adequacy with respect to M/S benefits across all applicable benefit classifications. Taken together, the factors, sources, and evidentiary standards, as well as the written materials and in-operation analysis, demonstrate that the network adequacy NQTL is applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Analysis Completed:	June 30, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Executive Director, Mental Health Parity Team • Executive Director, Network Provider Services • Lead Director, Quality and Performance Management (MBHO Accreditation), MSW, LSW

	• Lead Director, Quality and Performance Management (Health Plan Accreditation), MS, LPC, CN, LPN

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
FORMULARY DESIGN/TIERING
VIRGINIA: ADVANCED CONTROL FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Formulary Design/Tiering

A formulary is the list of generic and brand medications covered by a health benefit plan. The formulary contains tiers based on a drug's preferred or non-preferred status, and specialty or non-specialty status.

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefits Manager, CVS Caremark® (sometimes referred to as "PBM" or "Caremark"), including formulary management. The PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the Five (5) Tier Advanced Control Formulary – Aetna ("ACF-Aetna") formulary. The PBM's tiered formulary structure designates drugs as generic or brand, designates brand drugs as preferred or non-preferred, and designates drugs as specialty or non-specialty. Aetna further designates generic drugs as preferred and non-preferred and assigns cost share ranges to each tier. The Certificate of Coverage and Schedule of Benefits filed and approved by the state of Virginia support a variable range of member cost shares. There is no separate cost-share structure for MH/SUD drugs and M/S drugs. In accordance with 29 C.F.R. § 146.136(c)(3)(iii)(A), applicable to multi-tiered prescription benefits, the different levels of financial requirements are applied to different tiers of prescription benefits based on reasonable factors determined in accordance with rules relating to requirements for NQTLs and without regard to whether a drug is generally prescribed with respect to M/S benefits or MH/SUD benefits. The tiered benefit and cost-share design encourages generic utilization and lower pharmacy cost through copay differentials and encourages behaviors that will ultimately lead to appropriate utilization of cost-effective generics and preferred brand drugs.

In the prescription drug benefit classification, the following materials describe formulary design/tiering:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Covered services are based on the drugs in the **drug guide**. We exclude **prescription** drugs listed on the formulary exclusions list unless we approve a medical exception. The formulary exclusions

list is a list of **prescription** drugs not covered under the plan. This list is subject to change. If it is **medically necessary** for you to use a **prescription** drug that is not on this **drug guide**, you or your **provider** must request a medical exception. See the *Requesting a medical exception* section or just contact us.

The pharmacy may substitute a **generic prescription drug** for a **brand-name prescription drug**. Your cost share may be less if you use a **generic drug** when it is available.

Where your schedule of benefits fits in

The schedule of benefits shows any out-of-pocket costs you are responsible for when you receive **covered services** and any benefit limitations that apply to your plan. It also shows any **maximum out-of-pocket limits** that apply.

Schedule of Benefits: HSOB 11 SERFF Tracking #AETN-134117030

The Schedule of Benefits provides the member cost shares for covered services as outlined in the Certificate of Coverage.

2. DRUG GUIDE

The drug guide indicates the tier of covered drugs. It also provides definitions and other information for members. The most current version is publicly available at: Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers. The most current version is publicly available at: Aetna Provider Manual

4. POLICIES AND PROCEDURES

The following materials describe formulary design/tiering:

Document #	Title	Description
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
CPANDT-0002	CVS Caremark® National Pharmacy and Therapeutics (P&T) Committee	This policy defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T)

		Committee as well as requirements regarding conflicts of interest, meeting administration, and formulary decisions.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the file attached below contains all MH/SUD and M/S prescription drugs covered under the prescription drug benefit. These drugs are therefore subject to formulary design/tiering.

VIRGINIA: AETNA – ADVANCED CONTROL FORMULARY 2025 ACF Formulary Tiering 2025.xlsx	
Benefit classifications to which NQTL applies: a Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs labeled as Medical/Surgical in the attached Drug File	▪ Prescription Drugs labeled as MH or SUD in the attached Drug File

Step 2:Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

Tier 1 Drug Placement

A drug's placement in **Tier 1** indicates that it is a generic medication. Generic drugs are medications that have the same active ingredients, strength, and effectiveness as brand-name drugs, but they usually cost less. They are approved by the FDA and work the same way in the body, but they do not carry the brand name. This Tier 1 generic strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Generic Status	✓	✓

Generic Status means, drugs/medications that have the same active ingredients, strength, and effectiveness as brand-name drugs, but they usually cost less. They are approved by the FDA and work the same way in the body, but they do not carry the brand name. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Generic Status
- **Sources:**
  - Medi-Span Drug Database Brand Generic Reference

Additionally, generic drugs are placed on Tier 1 (as preferred generic) or Tier 3 (non-preferred generic). Indication of preferred and non-preferred generic status means the generic drug costs less (preferred) or more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 2 Drug Placement

A drug's placement in **Tier 2** indicates that it is considered a preferred brand-name medication. This designation is based on Caremark's preferred tier strategy, which evaluates brand/generic availability, and cost-effectiveness. The strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Financial Net Cost	✓	✓

Financial Net Cost means: The estimated total cost of a drug to the plan, calculated after accounting for wholesale acquisition cost (WAC), negotiated rebates, price concessions, or other financial incentives. Net cost is used as a financial factor as part of the assessment of a brand-name drug for inclusion as a preferred brand (Tier 2) on the formulary. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Pricing analyzed using a standard cost-model based on the drug's WAC minus rebates or another uniform pricing formula, applied consistently across all drugs within a therapeutic class.
- **Sources**
  - Medi-Span Drug Database Brand Generic Reference and WAC
  - Manufacturer Agreements (Applicable rebates)
  - Rx Claim PBM Database (WAC and script utilization by formulary)
  - FDA labeling

Tier 3 Drug Placement

A drug's placement in **Tier 3** indicates that it is a non-preferred brand. This Tier 3 strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Financial Net Cost	✓	✓

Financial Net Cost means: The estimated total cost of a drug to the plan, calculated after accounting for wholesale acquisition cost (WAC), negotiated rebates, price concessions, or other financial incentives. Net cost is used as a financial factor as part of the assessment of a brand-name drug for inclusion as a preferred brand (Tier 2) on the formulary. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Pricing analyzed using a standard cost-model based on the drug's WAC minus rebates or another uniform pricing formula, applied consistently across all drugs within a therapeutic class.
- **Sources**
  - Medi-Span Drug Database Brand Generic Reference and WAC
  - Manufacturer Agreements (Applicable rebates)
  - Rx Claim PBM Database (WAC and script utilization by formulary)
  - FDA labeling

Additionally, certain generic drugs are placed on Tier 3 (as non-preferred generic). which means the generic drug costs more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined to be non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 4 and Tier 5 Drug Placement

Factor	Applicable to M/S	Applicable to MH/SUD
Specialty Drug Status	✓	✓

Specialty drug designation is based on review and recommendation by a cross-functional clinical committee that evaluates clinical complexity, cost, and other relevant criteria. MH/SUD and M/S drugs designated as specialty medications are placed on Tiers 4 and 5, based upon whether the drug is identified as a preferred or non-preferred drug, as defined above. Drugs that are designated as specialty preferred are placed in Tier 4, and drugs designated as specialty non-preferred are placed in Tier 5. This strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

As set forth in Step 2, the factors used to determine a drug's tier placement are 1) generic status; 2) net cost; 3) specialty drug status. This section explains how these factors are used to determine drug tier placement. Based upon these factors, Aetna's PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the 5 tier ACF-Aetna formulary. The PBM's tiered formulary structure designates drugs as generic or brand, designates brand drugs as preferred or non-preferred, and designates drugs as specialty or non-specialty. Aetna further designates generic drugs as preferred and non-preferred, and assigns cost share ranges to each tier. The determination of which drugs are placed into each tier is based upon the same factors, strategies, and processes, and is evaluated consistently, regardless of therapeutic category, and without regard to whether the drug is used to treat M/S or MH/SUD conditions.

In making formulary decisions, Caremark considers clinical, financial, and market factors. All formulary decisions are approved by the CVS Caremark National Pharmacy & Therapeutics (P&T) Committee, which is an independent, external body. The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the formulary tiering process:

- The Formulary Administration team is comprised of analysts and pharmacists and oversees the standard template formulary development and management. The team monitors new drug databases, reviews the sources and evidentiary standards, conducts the drug evaluations, and provides information about placement on the formulary and tier assignment.
- The Formulary Review Committee (FRC) is comprised of individuals with expertise in pharmacy benefit management. This committee makes final recommendations for drug inclusions and tier placements for the CVS Caremark National Pharmacy and Therapeutics Committee's (P&T Committee) review and approval for template formularies. The FRC meets a minimum of 10 times per year and on an ad hoc basis as needed, to discuss and review proposals for formulary changes.
- The Clinical Formulary team is comprised of analysts and pharmacists and develops drug information documents. These documents are shared with other teams and experts involved in formulary development and the P&T Committee.
- The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds

and/or academic expertise regarding prescription drugs, and it meets at least quarterly. The committee's role with respect to tiering determinations is advisory in nature.

The FRC and P&T Committee members include experts from a variety of clinical fields including behavioral health, as well as experts in pharmacy benefits management.

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CVS Caremark Personnel Titles, Credentials and Committees Composition

The **Formulary Administration Department** oversees the standard template formulary development and management.

Job Title, Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Lead Director, Pharmacist
Sr Managers, Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Formulary Department** writes drug information materials in support of the P&T Committee.

Job Title, Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Lead Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analysts

The **Formulary Review Committee (FRC)** makes business recommendations. It includes individuals with expertise in pharmacy benefit management.

Voting Members Job Title, Credential	Business Unit
Lead Director Chairperson	Trade Relations
VP, Pharmacist	Product Development - Sales
Executive Director, MBA	Finance
Executive Director, MBA	Trade Relations
AVP, Pharmacist	Medical Affairs
Sr Manager, Pharmacist	Clinical Client Operations

The **P&T Committee**, an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs.

Voting Members, Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Internal Medicine
MD – Cardiology	MD – Infectious Disease

MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
PharmD – Gerontology	MD – Adult Psychiatry
MD – Gerontology	MD – Pediatric Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Advocate

Tier 1 Drug Placement

1. The generic status factor is used to determine tier placement as follows: A licensed PBM pharmacist reviews the drug specific source to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for Tier 1 placement. The drug database with Medi-Span information is queried by a licensed PBM pharmacist to locate the drug-specific Brand Generic Reference information section.

2. If the Brand Generic Reference is equal to "Y-GENERIC"; then the drug is generic is placed on Tier 1.

The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

The following scenario is assessed to identify if the standard is met. If **the scenario** applies to the drug, then the drug is considered a generic drug: a licensed PBM pharmacist reviews the Brand Generic Reference information to determine whether a drug qualifies as generic for Tier 1 placement. This scenario is consistently evaluated across all drug classes without regard to whether the drug is used to treat MH/SUD or M/S conditions.

Additionally, generic drugs are placed on Tier 1 (as preferred generic) or Tier 3 (non-preferred generic). Indication of preferred and non-preferred generic status means the generic drug costs less (preferred) or more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy are applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 2 Drug Placement

The Financial Net Cost factor is used to determine tier placement as follows: Individuals with expertise in pharmacy benefit management review the drug and disease-specific sources to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for Tier 2 preferred brand status. Therapeutic classes include brand and/or generic drugs that treat

similar conditions and compete with each other in the market. Net costs are calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.

The therapeutic categories are reviewed annually to evaluate any future changes based on new market entrants, changes in pricing or rebate contracts. Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable clinical and economic balance. Market factors such as supply chain durability (e.g., drug shortages) are also considered when no brands are preferred or only generics are covered. The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

Therapeutic Class Evaluation: Drugs are grouped and reviewed by therapeutic class. The therapeutic class framework allows for the identification of the product that offers the best overall value considering both clinical effectiveness, market conditions and net cost.

Net Cost Modeling: Net cost is calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.

Any of the following modeling scenarios could result in preferred brand designation:

1. Lowest net cost among brands (rebate-adjusted)
    - The brand offers the lowest WAC minus rebate among all brands in the class.
    - Generic alternatives may or may not exist within a therapeutic class.

2. Broader Indications
    - The brand has unique or broader indications relative to other brands in the drug category.
    - Net cost is competitive—even if not the lowest relative to other brands

3. Limited generic availability
    - A generic version exists but it may have supply constraints in the market which may require coverage of the brand
    - The brand is temporarily maintained as covered on formulary which may be in the preferred tier or non-preferred brand tier while the shortage of the generic version persists.

These scenarios are consistently evaluated across all drug classes without regard to whether the drug is used to treat MH/SUD or M/S conditions.

Tier 3 Drug Placement

The Financial Net Cost factor is used to determine tier placement as follows: Individuals with expertise in pharmacy benefit management review the drug and disease-specific sources to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for

Tier 2 preferred brand status, as mentioned above. Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable balance of clinical and economic value, as well as market factors such as supply chain durability (e.g., drug shortages) across the therapeutic class, either because no brands are preferred or only generics are covered. Non-preferred brand content is derived from the remaining products that are not placed on Tier 1 or 2. The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

The following scenario is assessed to identify if the standard is met. If the scenario applies to the brand drug, then the drug is assigned to Tier 3.

Net Cost Evaluation

- Products Net cost is calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.
- Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable balance of clinical and economic value
- Tier 3 non-preferred brand content is derived from remaining products that are not placed on Tier 1 or 2, which do not demonstrate the most favorable economic value.

This scenario is consistently evaluated across all drug classes without regard to whether the drug used to treat MH/SUD or M/S conditions.

Additionally, certain generic drugs are placed on Tier 3 (non-preferred generic). Indication of non-preferred generic status means the generic drug costs less more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

<u>Tier 4 and 5 Drug Placement</u>

Drug placement on Tiers 4 and 5 indicate that the drug is designated as a specialty drug. Specialty drug designation is based on review and recommendation by a cross-functional clinical committee that evaluates clinical complexity, cost, and other relevant criteria. Caremark adopts specialty drug status in connection with its standard formulary development process, and this designation is reflected in Aetna's formularies. MH/SUD and M/S drugs designated as specialty medications are placed on Tiers 4 and 5, based upon whether the drug is identified as a preferred or non-preferred drug, as defined above. Drugs that are designated as specialty and preferred are placed in Tier 4, and drugs designated as specialty and non-preferred are placed in Tier 5.

The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated, designated as specialty drug, and placed on Tiers 4 and 5. This

evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Relationship, ordering and weighting of multiple factors:

The factors listed above are interrelated, but apply to distinct formulary tiers, including Tiers 1-5 of the standard ACF-Aetna formulary. No factor is weighted more heavily than the other, and all operate together to ensure employment of a formulary design that encourages appropriate utilization of cost-effective drugs. The determination of which drugs are placed into each tier is based upon the same factors, strategies, and processes, and is evaluated consistently, regardless of therapeutic category, and without regard to whether the drug is used to treat M/S or MH/SUD conditions.

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering with respect to M/S drugs in the prescription drug benefit classification. CVS Caremark materials related to formulary design/tiering include:

Document #	Title	Description
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
CPANDT-0002	CVS Caremark National Pharmacy and Therapeutics (P&T) Committee	This policy defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee as well as requirements regarding Conflict of Interest, meeting administration, and formulary decisions.

The determination of which drugs are placed into each tier is based upon the same strategies and processes regardless of therapeutic category. Factors and evidentiary standards are applied

consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions.

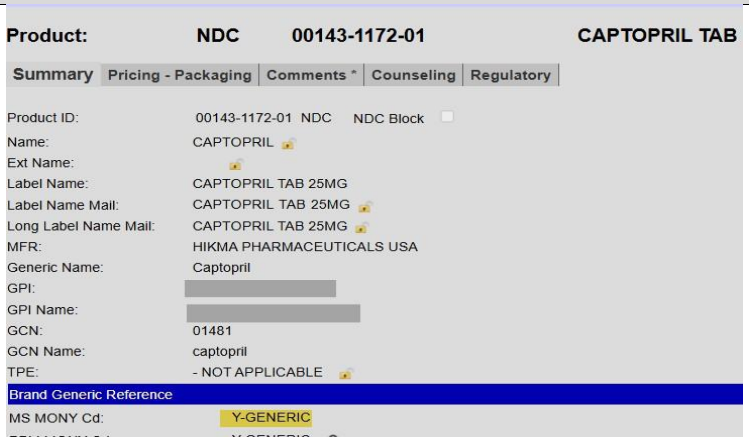
As written, the **Formulary Development and Management at CVS Caremark** document describes the underlying principles of the CVS Caremark formulary management and development process, and provides information about the groups involved in decision-making and oversight. There is no distinction between processes and committees used for M/S and MH/SUD drugs. The process for the development and management of the formulary, including committee members and meetings, is the same regardless of drug category.

As written, **Policy CPANDT-0002 CVS Caremark National Pharmacy and Therapeutics (P&T) Committee** defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee, including membership, meeting administration and formulary decisions. All members of the P&T Committee are independent contractors that are clinical experts from a variety of medical specialties that include both M/S and MH/SUD practitioners. Pursuant to this policy, the CVS Caremark National P&T Committee will review and approve drugs for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the formulary. Further, the CVS Caremark National P&T Committee will ensure that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states from a formulary and utilization management perspective. This policy applies generally to both M/S and MH/SUD drugs.

Additionally, the following provides a demonstration of how factors are applies to MH/SUD and M/S drugs for various tiers. The specific drugs in the following section were selected for illustrative purposes.

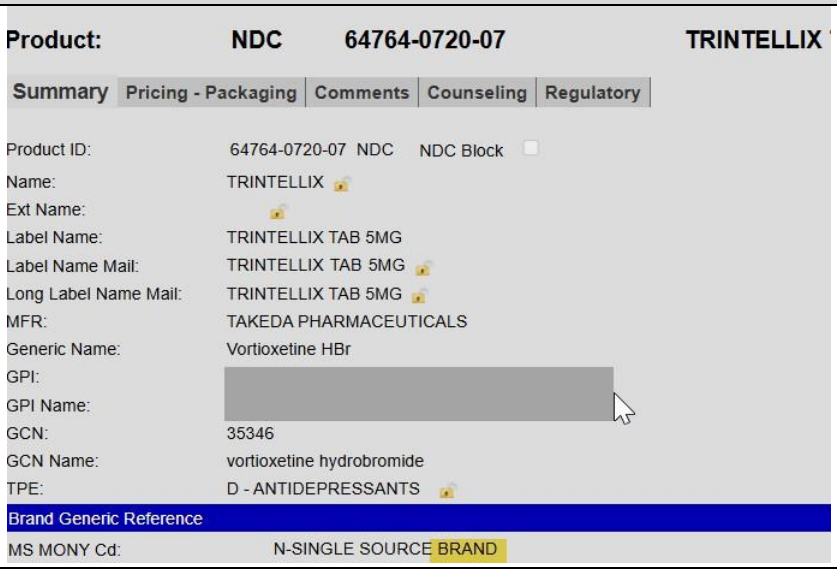
Tier 1 Drug Placement

The demonstration below illustrates how the factors are applied to MH/SUD and M/S drugs.

Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Captopril **MH/SUD:** No **Drug Group Description:** Antihypertensives		**Tier 1** Source confirms GENERIC This generic drug is placed in Tier 1.

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Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Duloxetine **MH/SUD:** Yes - MH **Drug Group Description:** Antidepressants		**Tier 1** Source confirms GENERIC This generic drug is placed in Tier 1.
Drug Name: Vivjoa **MH/SUD:** No **Drug Group Description:** Antifungals		Source confirms BRAND This brand drug is NOT placed in Tier 1.

Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Trintellix **MH/SUD:** Yes **Drug Group Description:** Antidepressants		Source confirms BRAND This brand drug is NOT placed in Tier 1.

Tier 2 Drug Placement

The following section illustrates how the preferred brand designation methodology is applied in practice using two representative drugs—one used to treat a MH/SUD condition, and one used to treat a M/S condition. These examples demonstrate the consistent application of the preferred brand designation criteria across therapeutic classes.

Note: While the methodology to determine brand coverage is applied consistently across all drug categories, the specific modeling scenarios may vary based on clinical and/or market dynamics—such as generic availability, market competition, or clinical indications. For example, many MH/SUD drug classes have high generic market penetration—often exceeding 90%—which significantly reduces the likelihood that a brand-name MH/SUD drug in that class will be selected for preferred status. In contrast, some MED/SURG drugs may not face the same degree of generic competition or may offer unique clinical attributes that justify a preferred designation despite higher cost. Accordingly, the differences in modeling scenarios reflect underlying market conditions and therapeutic class characteristics, not inconsistency in how the tiering methodology is applied.

The demonstration below illustrates how the factors are applied in practice to MH/SUD and M/S drugs.

Drug Name Qelbree
MH/SUD Yes
Category Attention Deficit Hyperactivity Disorder Non-Stimulants

Applicable Modeling Scenario # 1

ADHD Non-Stimulants	
BRAND	**Generic**
not available	clonidine ER
Intuniv	guanfacine ER
Onyda XR	*not available*
Qelbree	*not available*
Strattera	atomoxetine

- **Generic Alternatives**: atomoxetine, clonidine ER, guanfacine ER
- **Generic market share**: > 90% as measured by claims volume
- **Other brands**: Intuniv, Onyda XR, Strattera
- **WAC** derived from Medi-Span drug database:
  - Qelbree $520 (30-day supply)
  - Intuniv $370 (30-day supply) (Generic Available)
  - Onyda XR $480 (30-day supply)
  - Strattera $505 (30-day supply) (Generic Available)
- Any applicable rebates derived from manufacturer contracts
- Qelbree net costs are less by 9% to 16% compared to other branded products when the rebates are applied
- Generic costs are $52 for a 30-day supply and are less than preferred branded products (net of rebates) by a factor of 8 times

Tier Designation: Based on clinical factors, net costs of all products in the category, and market dynamics, Qelbree tier placement is preferred at the lowest branded tier, with all other brands at a higher tier or not covered. Generics are still the most preferred (Tier 1) agents.

Drug Name Austedo
MH/SUD No
Category Movement Disorders Huntington's Disease/Tardive Dyskinesia

Applicable Modeling Scenario: 2

Movement Disorders	
BRAND	**Generic**
Austedo	*not available*
Ingrezza	*not available*
Xenazine	tetrabenazine

- **Generic Alternatives**: tetrabenazine
- **Generic market share**: approximately 10% as measured by claims volume
- **Other brands**: Ingrezza, Xenazine
- **WAC** derived from Medi-Span drug database:
  - Austedo $7,960 (30-day supply)
  - Ingrezza $7,999 (30-day supply)
  - Xenazine $22,788 (30-day supply) (Generic Available)
- Applicable rebates derived from manufacturer contracts
- Based on WAC less rebates to derive lowest net cost, Ingrezza is the least expensive brand, with the net cost of Austedo 7% to 12% higher. Branded Xenazine has a net cost approximately 3.5 times higher (350%) than either of the other brand products.

- Generic costs for a 30-day supply of tetrabenazine are $4,715 and are less than branded products (net of rebates) by 27% to 30%
- Note, generic Tetrabenazine, which treats Huntington's Disease only, requires use multiple times daily vs. branded Austedo which treats both Huntington's Disease and Tardive Dyskinesia. Ingrezza only treats Tardive Dyskinesia.

Tier Designation: Austedo and Ingrezza are preferred at the lowest branded tier. Ingrezza is the lowest-net product in the class but only treats Tardive Dyskinesia; Austedo treats both Huntington's Disease and Tardive Dyskinesia. Factoring in the clinical profiles with the economic factors, both Ingrezza and Austedo are placed in a preferred brand tier, with Xenazine, which has a generic alternative, not covered.

Tier 3 Drug Placement

The demonstration below illustrates how the factors are applied in practice.

Drug Name Rexulti
MH/SUD Yes
Category Antipsychotics – Atypical

Applicable Modeling Scenario # 1

- **Generic Alternatives**: aripiprazole, asenapine, clozapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone
- **Generic market share**: 86% as measured by claims volume
- **Other brands**: Caplyta, Rexulti, Vraylar
- **WAC** derived from Medi-Span drug database:
  - Caplyta $1,672 (30-day supply)
  - Rexulti $1,485 (30-day supply)
  - Vraylar $1,444 (30-day supply)
- Any applicable rebates derived from manufacturer contracts
- All branded products with generic alternatives excluded
- Vraylar net costs are less by 10% to 21% compared to other branded products when the rebates are applied
- Rexulti net costs are less by 12% compared to other branded products when the rebates are applied
- Generic costs are $17 for a 30-day supply and are less than branded products (net of rebates) by a factor of 60 times

Antipsychotics - Atypical	
BRAND	**Generic**
Caplyta	*not available*
Rexulti	*not available*
Vraylar	*not available*
Abilify	aripiprazole
Versacloz	clozapine
Latuda	lurasidone
Zyprexa	olanzapine
Invega	paliperidone
Seroquel	quetiapine
Fanapt	*not available*
Risperdal	risperidone
Clozaril	clozapine
Secuado	*not available*
Saphris	asenapine
Opipza	*not available*
Geodon	ziprasidone

Tier Designation: Based on clinical factors, net costs of all products in the category, and market dynamics, Rexulti placement is Tier 3.

Summary

The written materials discussed herein, pertaining to formulary design/tiering for MH/SUD and M/S drugs, all apply equally to MH/SUD and M/S drugs, and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2. No separate policies, procedures or documents exist with respect to formulary design and tiering for MH/SUD drugs as compared to

M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply formulary design/tiering with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply formulary design/tiering with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering with respect to M/S drugs. A review was conducted to evaluate the formulary status and tier assignment of MH/SUD and M/S drugs.

Testing Methodology

The input drug coverage extract file was processed and analyzed as follows:

- Using the Medi-Span Generic Product Identifier (GPI) therapeutic classification system, drugs with the same GPI code, brand/generic code, dosage form & strength, name, and route of administration were counted as one.
- Drugs were grouped into MH, SUD and M/S drug types, organized into formulary tiers, counted, and the totals were used to calculate the percentages of drugs in each tier by type.
- Drugs were grouped by preferred tiers, counted, and the totals were used to calculate the percentages with this preferred tier drug status.

To calculate the percent of drug type in each tier, the formula used is (X/Y)*100, where:

- X = the count of drugs of each type by tier
- Y = the total count of that drug type in the formulary

To calculate the percent of drug type with preferred formulary status, the formula used is [(A+B+C+…)/Y]*100, where:

- A, B, C, ... = the count of drugs of each type in preferred tiers
- Y = the total count of that drug type in the formulary

Results

The output formulary file attached in Step1, part 2 contains the drugs, formulary status, and tier assignment for the ACF-Aetna Formulary:

Formulary Tier Descriptions

- Tier 1 = Preferred Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands & Generics
- Tier 4 = Preferred Specialty
- Tier 5 = Non-Preferred Specialty

Formulary Tiering by Drug Type

Aetna - Advanced Control Formulary 2025

Drug Type	Results												
MED/SURG	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	0	1938	325	824	681	301	0	0	0	0	0	4069	72.4%
	0.0%	47.6%	8.0%	20.3%	16.7%	7.4%	0.0%	0.0%	0.0%	0.0%	0.0%		
MH	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	0	526	35	130	24	8	0	0	0	0	0	723	80.9%
	0.0%	72.8%	4.8%	18.0%	3.3%	1.1%	0.0%	0.0%	0.0%	0.0%	0.0%		
SUD	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	0	90	6	9	2	1	0	0	0	0	0	108	90.7%
	0.0%	83.3%	5.6%	8.3%	1.9%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%		

In operation, the analysis and testing of the tiers shows that more MH/SUD drugs are placed within preferred tiers than M/S drugs, revealing that the factors and the sources are not used differently or more stringently with respect to MH/SUD compared to M/S drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs. Based upon review of the data and information addressed herein, Aetna may conclude that, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying formulary design/tiering with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying formulary design/tiering with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of its prescription drug benefit to its PBM, including formulary management. In the prescription drug benefit classification, a formulary is the list of generic and brand medications covered by a health benefit plan. The formulary contains tiers based on a drug's preferred or non-preferred status, and specialty or non-specialty status. The PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the 5 Tier ACF-Aetna formulary, and Aetna assigns cost share ranges to each tier. The Certificate of Coverage and Schedule of Benefits filed and approved by the state of Virginia support a variable range of member cost shares. There is no separate cost-share structure for MH/SUD drugs and M/S drugs.

Step 2 identified the factors that are used to design and apply formulary design/tiering to M/S and MH/SUD drugs, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of formulary design/tiering; there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, as written, to M/S and MH/SUD drugs, and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to formulary design/tiering in a comparable manner and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that formulary design/tiering is designed and applied in a comparable manner to MH/SUD and M/S drugs.

More specifically, as demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining formulary design/tiering for M/S and MH/SUD drugs. An as-written comparative analysis shows that no separate policies or procedures exist with respect to formulary design/tiering for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs, and the factors, sources and evidentiary standards are used in a comparable and no more stringent manner to determine formulary tier placement for MH/SUD and M/S drugs. This information and review demonstrate that, as written, formulary design/tiering is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

In addition, as demonstrated in **Step 5**, in operation, formulary design/tiering is applied in a comparable manner for both M/S and MH/SUD drugs. Testing of the formulary tiers and preferred drug composition shows that overall, a higher percentage of MH drugs and a higher percentage of SUD drugs are covered on preferred or lower cost tiers, compared to M/S. Accordingly, the factors, evidentiary standards and sources are not used differently or more stringently with respect to MH/SUD compared to M/S drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying formulary design/tiering to M/S drugs. Moreover, in accordance with 29 C.F.R. § 146.136(c)(3)(iii)(A), applicable to multi-tiered prescription benefits, Aetna has demonstrated that different levels of financial requirements are applied to different tiers of prescription benefits based on reasonable factors determined in accordance with rules relating to requirements for NQTLs and without regard to whether a drug is generally prescribed with respect to M/S benefits or with respect to MH/SUD benefits.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Aetna Health Plan Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Health Plan Pharmacy (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: PRIOR AUTHORIZATION
VIRGINIA: ADVANCED CONTROL FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Prior Authorization

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® ("Caremark" or "PBM"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Prior authorization (hereinafter sometimes "PA") refers to a process that requires the prescribed use of a drug to be evaluated against a predetermined set of objective criteria before the prescription can be filled under a benefit plan. Prior authorization criteria documents define the circumstances under which a prior authorization medication should be paid under a prescription benefit plan. Prior authorization of prescription drugs is conducted by the Caremark Prior Authorization Department using pre-established medical necessity guidelines developed by Caremark.

In the prescription drug benefit classification, the following materials describe prior authorization:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Precertification
You need pre-approval from us for some **covered services**. Pre-approval is also called **precertification**.

Step therapy is a type of **precertification** where you must try one or more prerequisite drugs before a step therapy drug is covered. A 'prerequisite' is something that is required before something else. Prerequisite drugs are FDA-approved, may cost less and treat the same condition. If you don't try the prerequisite drugs first, the step therapy drug may not be covered.

Contact us or go online to get the most up to date **precertification** requirements and list of step therapy drugs.

Requesting a medical exception
Sometimes you or your **provider** may ask for a medical exception to get coverage for drugs that are not covered [or for **brand name** or **specialty drugs** or for which coverage was denied through **precertification** or **step therapy**. You, someone who represents you or your **provider** can contact us. You will need to provide us with clinical documentation. For directions on how you can submit a request for a review:
Call the toll-free number on your ID card
Go online at https://www.aetna.com
Submit the request in writing to:

CVS Health
ATTN: Aetna PA
1300 E Campbell Road
Richardson, TX 75081

2. DRUG GUIDE

The Drug Guide provides important information for members pertaining to prior authorization, including the medications requiring precertification. This list is subject to change. The most current version is publicly available at: Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information pertaining to prior authorization. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies describe prior authorization:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide attached below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: ADVANCED CONTROL FORMULARY 2025 DRUG GUIDE	
2025_Advanced_Control_Plan_Aetna.pd	
Benefit classifications to which NQTL applies: ✔ **Prescription Drug**	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**

▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) including a drug or drug class in prior authorization programs; and b) development of coverage criteria. Aetna's PBM develops standard formularies and assigns utilization management designations such as prior authorization, step therapy and quantity limits based on clinical, safety and cost-effectiveness factors supported by nationally recognized evidence and guidelines.

(a) Factors for including a drug or drug class in prior authorization programs.

The determination of which drugs are subject to utilization management, including prior authorization, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including prior authorization, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in prior authorization programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓

Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2) Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information

  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia

  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards**:
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence

- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
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  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)
  - Healthcare.gov
  - NCQA.org
  - URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**

- FDA Orange Book
- FDA Purple Book
- FDA Drug-specific product label
- FDA Online Label Repository
- FDA Drug Trial Snapshot
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- CVS Caremark® Drug Claims Utilization
- Manufacturer Agreements or Rebate Contracts
- Internal business partner consultation

(b) Factors for the development of coverage criteria

The development of coverage criteria for drugs that require prior authorization is based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**

  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
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  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2) Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
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  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
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  - CVS Caremark® Drug Trend Report
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  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
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- Healthcare.gov
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Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts

- Internal business partner consultation

<u>Step 3</u>: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including prior authorization, and the development of coverage criteria for drugs that require prior authorization, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require prior authorization for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in prior authorization programs and upon which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including prior authorization, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs. The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse

Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy
Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a Caremark Medical Director, and by external clinical experts whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the clinical criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to M/S drugs in the prescription drug benefit classifications. Caremark policies related to prior authorization include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization,

	Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark® Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure document the requirements for the prior authorization process for plans subject to Virginia (IN) state laws.

INCLUDING A DRUG OR DRUG CLASS IN PRIOR AUTHORIZATION PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in prior authorization programs and upon which development of coverage criteria is based are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in prior authorization programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (prior authorization, step therapy, quantity limits) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD

disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary source, must support the coverage conditions of the prior authorization requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard CVS Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply prior authorization to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.

- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The type(s) of NQTL (prior authorization, step therapy and/or quantity limits) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.
- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.
- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC

standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs (including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION- PRIOR AUTHORIZATION DESIGN PROCESS DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's (PA, ST, QL) development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to

the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.

v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.

vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustration only, and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil) **MH/SUD:** Yes **M/S:** No **Therapeutic Category:** Stimulants (Miscellaneous)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • Narcolepsy
	  • Shift Work Disorder (SWD)

Step 3	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established

in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective.
  Accessed 06-09-25
- Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil).
  Accessed 06-10-25

- Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy.
- Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
  Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

	Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil). Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 **Off-label Prescribing Patterns**. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. ◦ CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.
Step 5	The sources that were used and documented for armodafinil include: ◦ Prescribing information for armodafinil (Nuvigil) ◦ Drug information Databases and compendia ▪ Lexicomp AHFS DI ▪ Micromedex ◦ Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.
	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification
	  • Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy.
	  • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil.
	• Reason for Type of NQTL
	  • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy.
	  • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil):
	  ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days
	  ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days

	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION

Caremark performs utilization management on Aetna's behalf. Its policies are used to determine operational aspects of prior authorization. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting prior authorization for both M/S and MH/SUD drugs. This policy documents the requirements for the prior authorization process for plans subject to Virginia (VA) laws. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure
The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.
   i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.
   i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

   ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

   i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

   ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

   iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

   iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals
Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded

to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:
    a. Urgent PA Reviews will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.
2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.
    a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
    b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    c. Notification will be provided within 24 hours of making the adverse determination.
3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:
    a. Urgent step therapy requests will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;

ii. The reason(s) for the Adverse Determination;

iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;

iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;

v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;

vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.

vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs require prior authorization, the development of coverage criteria, and the process of conducting prior authorization, all apply equally to MH/SUD and M/S drugs and demonstrate

use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to prior authorization for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply prior authorization with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply prior authorization with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to M/S drugs.

As discussed in Step 4 above, the application of prior authorization within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for prior authorization—including submission requirements, review timelines, clinical documentation standards, and appeal processes—are identical across both benefit categories. The operation of the prior authorization process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation analysis is conducted by reviewing the following:

- Prior Authorization Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – PRIOR AUTHORIZATIONS

Evaluation of approval/denial rates for M/S and MH/SUD prior authorization requests is one measure that can evaluate whether prior authorization is applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects prior authorization decisions for MH/SUD and M/S drugs on the **Aetna Advanced Control Formulary for 2025**.

The data reflects the total number of decisions and the total number of decisions that were approved and denied.

Approval/Denial Rates – Prior Authorizations			
VIRGINIA - Aetna Advanced Control Formulary – 2025			
Drug Type	MED/SURG	MH	SUD
Total Requests	1,902	248	-
Total Approvals	1,430	218	-
Total Denials	472	30	-
Approval Percent	75.2%	87.9%	0.0%
Denial Percent	24.8%	12.1%	0.0%
Average TAT in Days	0.137	0.088	-

This data reflects that overall, **87.9%** of prior authorizations for MH drugs were approved, and **75.2%** of M/S drugs were approved. There were no prior authorization requests for SUD drugs. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs was less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying prior authorization to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its PBM, Caremark, audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA

requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or M/S condition.

- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In summary, based upon review of the data and information addressed herein, Aetna concludes that the processes, strategies, evidentiary standards or other factors used in designing and applying prior authorization with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying prior authorization with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its Pharmacy Benefit Manager, CVS Caremark®, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Prior authorization refers to a process that requires the prescribed use of a drug to be evaluated against a predetermined set of objective criteria before the prescription can be filled under a benefit plan. Prior authorization criteria documents define the circumstances under which a prior authorization medication should be paid under a prescription benefit plan.

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to prior authorization, and the development of coverage criteria for drugs that require prior authorization, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of prior authorization. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to prior authorization and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to prior authorization in a comparable manner, and the MH/SUD drugs to which prior authorization applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The

comparative analysis conducted above demonstrates that prior authorization is designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to prior authorization, the development of coverage criteria for drugs that require prior authorization, and the process of conducting prior authorization. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply prior authorization. That analysis shows that no separate policies or procedures exist with respect to prior authorization for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying prior authorization in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. CVS Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, prior authorization is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, prior authorization is applied in a comparable manner for both M/S and MH/SUD drugs. The application of prior authorization within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs. The operational procedures for prior authorization are identical across both benefit categories. The operation of the prior authorization process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of prior authorization approval and denial rates, which demonstrated lower rates of prior authorization denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating prior authorization coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases

demonstrated that the process for reviews was consistent across all prior authorization requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying prior authorization to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan(Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: QUANTITY LIMITS
VIRGINIA: ADVANCED CONTROL FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Quantity Limits

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® (hereinafter "PBM" or "Caremark"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Quantity limits (hereinafter sometimes "QL") refers to a limitation that establishes a maximum quantity of a drug that is covered over a specified period of time. In the prescription drug benefit classification, the following materials describe quantity limits:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Prescription drugs covered under this plan are subject to misuse, waste or abuse utilization review by us, your **[provider]** or your network pharmacy. The outcome of the review may include:

- Limiting coverage of a drug to one prescribing **[provider]** or one network pharmacy
- Quantity, dosage or day supply limits
- Requiring a partial fill or denial of coverage]

2. DRUG GUIDE

The Drug Guide provides important information for members pertaining to quantity limits, including the drugs subject to quantity limits and information about exceptions to quantity limit requirements. The most current version is publicly available at:

Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

CONTAINS PROPRIETARY, CONFIDENTIAL INFORMATION AND TRADE SECRETS OF AETNA. THIS INFORMATION IS EXEMPT FROM STATE OR FEDERAL FREEDOM OF INFORMATION ACT REQUESTS.

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information about drugs subject to quantity limits and exceptions to quantity limit requirements. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. They also describe the medical exception clinical coverage criteria for drugs subject to quantity limits. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies pertain to quantity limits:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management NQTLs (prior authorization, quantity limits, and step therapy) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.

at CVS Caremark®		
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process, including as applicable for prior authorization requests for exceptions to quantity limits, for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: ADVANCED CONTROL FORMULARY 2025 DRUG GUIDE	
2025_Advanced_Control_Plan_Aetna.pd	
Benefit classifications to which NQTL applies: ✔ Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following section identifies and defines the factors, evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) quantity limit programs; and b) development of coverage criteria. Aetna's PBM, Caremark, maintains standard utilization management (UM) policies that include quantity limits and clinical criteria developed based on nationally recognized clinical guidelines, FDA labeling, and evidence-based literature.

a. Factors for including a drug or drug class in quantity limits programs.

The determination of which drugs are subject to utilization management, including quantity limits, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including quantity limits, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in quantity limits programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Evidence-based Uses and Clinical Efficacy	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Cost Effectiveness	✓	✓

Evidence-based Uses and Clinical Efficacy means: 1) Potentially unsafe and ineffective dose escalation - Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule; Drug or drug class has potential for being prescribed for periods of time exceeding the recommended duration of therapy or when therapy ceases to provide benefit; Drug or drug class has no evidence or data regarding efficacy at doses above the FDA approved limit; Drug or drug class has evidence that increasing the dose past the FDA approved limits does not provide improved efficacy. 2) Dose Optimization - Drug or drug class has evidence that the number of dosage units can be reduced by using a higher strength formulation of the drug without compromising efficacy. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot

- Disease specific Clinical Practice Guideline Protocols
- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon .The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, including drugs that may be equally efficacious and less costly; 2) High utilization - Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits. An NQTL may be applied to ensure dosing follows the FDA approved limit and is in alignment with the FDA labeled indication(s).The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

b. Factors for the development of coverage criteria

The development of coverage criteria for drugs subject to quantity limits are based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Evidence-based Uses and Clinical Efficacy	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓

Cost Effectiveness	✓	✓

Evidence-based Uses and Clinical Efficacy means: 1) Potentially unsafe and ineffective dose escalation - Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule; Drug or drug class has potential for being prescribed for periods of time exceeding the recommended duration of therapy or when therapy ceases to provide benefit; Drug or drug class has no evidence or data regarding efficacy at doses above the FDA approved limit; Drug or drug class has evidence that increasing the dose past the FDA approved limits does not provide improved efficacy. 2) Dose Optimization - Drug or drug class has evidence that the number of dosage units can be reduced by using a higher strength formulation of the drug without compromising efficacy. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time,

forgetting to take a dose, or stopping the medication too soon. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
    Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, including drugs that may be equally efficacious and less costly; 2) High utilization - Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits. An NQTL may be applied to ensure dosing follows the FDA approved limit and is in alignment with the FDA labeled indication(s). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations

  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including quantity limits, and the development of coverage criteria for drugs that require quantity limits, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require quantity limits for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in quantity limits programs and upon

which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Evidence-based uses and clinical efficacy; (2) Risk of abuse, misuse, addiction or diversion; (3) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including quantity limits, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs.

The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration

Exec Director, Pharmacist	Medicare Gov Pharmacy
Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a Caremark Medical Director, and by external clinical experts whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease

MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to M/S drugs in the prescription drug benefit classifications. Caremark policies related to quantity limits include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) non-quantitative treatment limitations (NQTLs), to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.

FormDevMgmt.pdf	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process, including as applicable for prior authorization requests for exceptions to quantity limits, for plans subject to Virginia (VA) state laws.

INCLUDING A DRUG OR DRUG CLASS IN QUANTITY LIMITS PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in quantity limits programs and upon which development of coverage criteria are based are: (1) Evidence-based uses and clinical efficacy; (2) Risk of abuse, misuse, addiction or diversion; (3) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in quantity limits programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (prior authorization, step therapy or quantity limits) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary source, must support the coverage conditions of the quantity limits requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard CVS Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within CVS Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply quantity limits to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.
- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The type(s) of NQTL (prior authorization, quantity limit or step therapy) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.
- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.

- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs (including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION- UTILIZATION MANAGEMENT DESIGN PROCESS DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets

parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.
   v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.
   vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustrative purposes only and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil)

	MH/SUD: Yes **M/S:** No **Therapeutic Category:** Stimulants (Miscellaneous)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • Narcolepsy
	  • Shift Work Disorder (SWD)

Step 3.	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective. Accessed 06-09-25 • Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil). Accessed 06-10-25 ▪ Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy. • Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893. Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil).
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance.
  Accessed 06-09-25

Off-label Prescribing Patterns. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications.
  Accessed 06-09-25

	• Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. • CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.

Step 5	The sources that were used and documented for armodafinil include:
	• Prescribing information for armodafinil (Nuvigil)
	• Drug information Databases and compendia
	  • Lexicomp AHFS DI
	  • Micromedex
	• Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.
	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification

	• Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy. • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil. • Reason for Type of NQTL • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy. • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil): ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days
	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION (INCLUDING QUANTITY LIMITS EXCEPTION REQUESTS)

Caremark performs utilization management on Aetna's behalf. Its policies are used to determine operational aspects of prior authorization. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting prior authorization for both M/S and MH/SUD drugs. This policy documents the requirements for the prior authorization process for plans subject to Virginia (VA) laws. Physicians, patients, or a person appointed to manage the patient's care designated as an authorized representative can request prior authorization or exceptions to quantity limits, and prior authorization requests for exceptions to quantity limits are handled pursuant to this policy which applies equally to MH/SUD and M/S drugs. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.

i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.

i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:

a. Urgent PA Reviews will be completed within 24 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48

hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.

2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.

a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

c. Notification will be provided within 24 hours of making the adverse determination.

3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:

a. Urgent step therapy requests will be completed within 24 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;
ii. The reason(s) for the Adverse Determination;
iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;
iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;
v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;
vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.
vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs are subject to quantity limits, the development of coverage criteria, and the process of conducting prior authorization of requests for exceptions to quantity limits, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to quantity limits for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply quantity limits with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply quantity limits with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to M/S drugs.

As discussed in Step 4 above, the application of quantity limits within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for quantity limits exception requests are identical across both benefit categories. The operation of the quantity limits process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation comparative analysis is conducted by reviewing the following:

- Prior Authorization/Quantity limits Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – QUANTITY LIMITS EXCEPTIONS

Evaluation of denial rates for M/S and MH/SUD quantity limits exceptions requests is one measure that can evaluate whether quantity limits are applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects quantity limits decisions for MH/SUD and M/S drugs on the **Aetna Advanced Control Formulary for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied available through the date of this submission.

Approval/Denial Rates – Quantity Limits Exceptions			
VIRGINIA - Aetna Advanced Control Formulary – 2025			
Drug Type	**MED/SURG**	**MH**	**SUD**
Total Requests	1,663	169	7
Total Approvals	1,101	136	6
Total Denials	562	33	1
Approval Percent	66.2%	80.5%	85.7%
Denial Percent	33.8%	19.5%	14.3%
Average TAT in Days	0.147	0.141	0.014

This data reflects that overall, **80.5%** of quantity limits exceptions for MH drugs were approved, and **66.2%** of M/S drugs were approved. **85.7%** of quantity limits exception requests for SUD drugs were approved. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs were less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying utilization management to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its delegate, Caremark, audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or Med Surg condition.
- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria

questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In summary, based upon review of the data and information addressed herein, Aetna may conclude that the processes, strategies, evidentiary standards or other factors used in designing and applying utilization management, including quantity limits, with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying quantity limits with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its Pharmacy Benefit Manager, Caremark, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Quantity limits refers to a limitation that establishes a maximum quantity of a drug that is covered over a specified period

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to utilization management including quantity limits, and the development of coverage

criteria for drugs that require quantity limits, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of quantity limits. As noted in **Step 3**, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to quantity limits and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to quantity limits in a comparable manner, and the MH/SUD drugs to which quantity limits applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that quantity limits are designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4,** as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to quantity limits, the development of coverage criteria for drugs that require quantity limits, and the process of conducting prior authorization for quantity limits exception requests. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply quantity limits. That analysis shows that no separate policies or procedures exist with respect to quantity limits for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying quantity limits in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, quantity limits are designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and are not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, quantity limits are applied in a comparable manner for both M/S and MH/SUD drugs. The application of quantity limits within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs.

Further, the operational procedures for quantity limits are identical across both benefit categories. The operation of the prior authorization process for quantity limits demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of quantity limits approval and denial rates, which demonstrated lower rates of denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating to utilization management coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases demonstrated that the process for reviews was consistent across all utilization management requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying quantity limits to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: STEP THERAPY
VIRGINIA: ADVANCED CONTROL FORMULARY – AETNA 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Step Therapy

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® (hereinafter sometimes "PBM" or "Caremark"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Step Therapy (hereinafter sometimes "ST") refers to criteria that define the circumstances under which a drug requiring prerequisite therapy will be systematically paid under a prescription benefit or reviewed through the prior authorization process. For MH/SUD and M/S drugs subject to a step therapy requirement, prior authorization is required. Prior authorization of prescription drugs subject to a step therapy requirement is conducted by the Caremark Prior Authorization Department using pre-established medical necessity guidelines developed by Caremark. In the prescription drug benefit classification, the following materials describe step therapy:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Step therapy is a type of **precertification** where you must try one or more prerequisite drugs before a step therapy drug is covered. A 'prerequisite' is something that is required before something else. Prerequisite drugs are FDA-approved, may cost less and treat the same condition. If you don't try the prerequisite drugs first, the step therapy drug may not be covered.

Contact us or go online to get the most up to date **precertification** requirements and list of step therapy drugs.

2. DRUG GUIDE

The Drug Guide includes important information for members pertaining to step therapy, including identification of M/S and MH/SUD medications requiring step therapy. The most current version is publicly available at:

Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information pertaining to step therapy. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies describe step therapy:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management programs.

CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the utilization management process for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: ADVANCED CONTROL FORMULARY 2025 DRUG GUIDE 2025_Advanced_Control_Plan_Aetna.pd	
Benefit classifications to which NQTL applies: ✔ Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) including a drug or drug class in step therapy programs; and b) development of coverage criteria. Caremark develops standard formularies and assigns utilization management designations such as prior authorization, step therapy, and quantity limits based on clinical, safety and cost-effectiveness factors supported by nationally recognized evidence and guidelines.

(a) Factors for including a drug or drug class in step therapy programs.

The determination of which drugs are subject to utilization management, including step therapy, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including step therapy, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in step therapy programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a

drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2)Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label

- FDA Online Label Repository
- FDA Drug Safety-related Labeling Changes (SrLC)
- FDA Drug Trial Snapshot
- Disease specific Clinical Practice Guideline Protocols
- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong

time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**

- CMS.gov
- Individual state regulations sites
- Health and Human Services (HHS.gov)
- Healthcare.gov
- NCQA.org
- URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts

- Internal business partner consultation

(b) Factors for the development of coverage criteria

The development of coverage criteria for drugs that require step therapy is based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology

- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2)Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR),

Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information

- Clinical evidence determined to be experimental, investigational or unproven
- Clinical Practice Guidelines
- Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)

- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs

- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
- CVS Caremark® Drug Trend Report
- Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)
  - Healthcare.gov
  - NCQA.org
  - URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population

and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including step therapy, and the development of coverage criteria for drugs that require step therapy, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require step therapy for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in step therapy programs and upon

which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including step therapy, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs. The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark® template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy

Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a CVS Caremark Medical Director, and by external clinical experts. whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the clinical criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology

MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to M/S drugs in the prescription drug benefit classifications. Caremark policies related to step therapy include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs UM NQTLs (prior authorization, step therapy, quantity limits), to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management programs.

CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the utilization management process for plans subject to Virginia (VA) state laws.

INCLUDING A DRUG OR DRUG CLASS IN STEP THERAPY PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in step therapy programs and upon which development of coverage criteria is based are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in step therapy programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (step therapy, quantity limits, prior authorization) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary

source, must support the coverage conditions of the step therapy requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark® policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply step therapy to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.
- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The

type(s) of NQTL (prior authorization, step therapy, quantity limits) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.

- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.
- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs

(including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION-
UTILIZATION MANAGEMENT DESIGN PROCESS DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's (PA, ST, QL) development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.
   v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.

vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustration only, and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil) **MH/SUD:** Yes **M/S:** No **Therapeutic Category:** Stimulants (Misc.)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • NarcolepsyShift Work Disorder (SWD)

Step 3.	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use. Sources reviewed for this factor:

	• Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective. Accessed 06-09-25 • Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil). Accessed 06-10-25 ▪ Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy. • Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893. Accessed 06-10-25 **Patient Population/Monitoring Considerations/Treatment Complexity** – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information. Accessed 06-09-25 • Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring. • 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504. Accessed 06-10-25 • 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276. Accessed 06-10-25 • 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023. Accessed 06-10-25 • 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394. Accessed 06-10-25 • 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945. Accessed 06-10-25 **Risk of Abuse, Misuse, Addiction or Diversion**- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing.

	Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil). Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 **Off-label Prescribing Patterns**. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. • CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.

Step 5	The sources that were used and documented for armodafinil include:
	• Prescribing information for armodafinil (Nuvigil)
	• Drug information Databases and compendia
	  • Lexicomp AHFS DI
	  • Micromedex
	• Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.

	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification
	  • Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy.
	  • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil.
	• Reason for Type of NQTL
	  • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy.
	  • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil):
	  ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days
	  ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days

	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION (INCLUDING FOR MH/SUD AND M/S DRUGS THAT REQUIRE STEP THERAPY)

Caremark performs utilization management on behalf of Aetna. Its policies are used to determine operational aspects of prior authorization conducted for drugs that require step therapy. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting reviews for M/S and MH/SUD drugs, including drugs that have a step therapy requirement. This policy documents the requirements for

the prior authorization process, including for step therapy, for plans subject to Virginia (IN) laws. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.
    i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.
    i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

    ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

    i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

    ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

    iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

    iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:
    a. Urgent PA Reviews will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.
2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.
    a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
    b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    c. Notification will be provided within 24 hours of making the adverse determination.
3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:
    a. Urgent step therapy requests will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the

missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;

ii. The reason(s) for the Adverse Determination;

iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;

iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;

v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;

vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.

vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs require step therapy, the development of coverage criteria, and the process of conducting prior authorization of MH/SUD and M/S drugs subject to a step therapy requirement, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to step therapy for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply step therapy with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other

factors used to design and apply step therapy with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to M/S drugs.

As discussed in Step 4 above, the application of step therapy within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for prior authorization of M/S and MH/SUD drugs that require step therapy are identical across both benefit categories. The operation of the step therapy process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation analysis is conducted by reviewing the following:

- Prior Authorization/Step Therapy Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – STEP THERAPY

Evaluation of denial rates for M/S and MH/SUD step therapy requests is one measure that can evaluate whether step therapy is applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects step therapy decisions for MH/SUD and M/S drugs on the **Aetna Advanced Control Formulary – Aetna for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied.

Approval/Denial Rates – Step Therapy Exceptions			
VIRGINIA - Aetna Advanced Control Formulary – 2025			
Drug Type	MED/SURG	MH	SUD
Total Requests	707	50	-
Total Approvals	625	43	-
Total Denials	82	7	-
Approval Percent	88.4%	86.0%	0.0%
Denial Percent	11.6%	14.0%	0.0%
Average TAT in Days	0.134	0.213	-

This data reflects that overall, **86.0%** of requests for MH drugs were approved, and **88.4%** of requests for M/S drugs were approved. There were no ST exception requests for SUD drugs. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs was less than 24 hours. While this data reflects that overall, MH/SUD drugs were approved at a lower percentage rate than M/S drugs, this data is not indicative of step therapy being applied in a manner that is more stringent for MH/SUD drugs than M/S drugs. First, the higher rate of denials for MH/SUD drugs is not statistically significant because the sample size for MH/SUD drugs **(50)** is too small to draw statistically valid conclusions regarding parity compliance or the stringency of UM application. Second, MHPAEA guidance has consistently provided that operational outcomes are not determinative of parity compliance. While these rates reflect differences in approval and denial outcomes between the two categories of drugs, they do not, in themselves establish non-compliance with mental health parity, as variations in outcomes may result from differences in prescribing patterns, clinical appropriateness, regulatory considerations, or formulary design rather than the application of more restrictive standards to MH/SUD drugs

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying utilization management to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its delegate Caremark audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.

- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or Med Surg condition.
- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In sum, based upon review of the data and information addressed herein, Aetna concludes that the processes, strategies, evidentiary standards or other factors used in designing and applying step therapy with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying step therapy with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its PBM, Caremark, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Step therapy refers to criteria that define the circumstances under which a drug requiring prerequisite therapy will be systematically paid under a prescription benefit or reviewed through the prior authorization process.

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to step therapy requirements, and the development of coverage criteria for drugs that require step therapy, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of step therapy. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to step therapy and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to step therapy in a comparable manner, and the MH/SUD drugs to which step therapy applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that step therapy is designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to step therapy, the development of coverage criteria for drugs that require step therapy, and the process of conducting prior authorization for M/S and MH/SUD drugs subject to step therapy. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply step therapy. That analysis shows that no separate policies or procedures exist with respect to step therapy for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying step therapy in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, step therapy is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, step therapy is applied in a comparable manner for both M/S and MH/SUD drugs. The application of step therapy within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs. Further, the operational procedures for conducting prior authorization for drugs subject to step therapy are identical across both benefit categories. The operation of the prior authorization process for step therapy demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of quantity limits approval and denial rates. While this data reflects that overall, MH/SUD drugs were approved at a lower percentage rate than M/S drugs, this data is not indicative of step therapy being applied in a manner that is more stringent for MH/SUD drugs than M/S drugs. First, the higher rate of denials for MH/SUD drugs is not statistically significant because the sample size for MH/SUD drugs (50) is too small to draw statistically valid conclusions regarding parity compliance or the stringency of UM application and the decision-making turnaround time for both MH/SUD and M/S drugs was less than 24 hours. Second, MHPAEA guidance has consistently provided that operational outcomes are not determinative of parity compliance. While these rates reflect

differences in approval and denial outcomes between the two categories of drugs, they do not, in themselves establish non-compliance with mental health parity, as variations in outcomes may result from differences in prescribing patterns, clinical appropriateness, regulatory considerations, or formulary design rather than the application of more restrictive standards to MH/SUD drugs. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating utilization management coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases demonstrated that the process for reviews was consistent across all utilization management requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying step therapy to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
FORMULARY DESIGN/TIERING
VIRGINIA: EXCHANGE FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Formulary Design/Tiering

A formulary is the list of generic and brand medications covered by a health benefit plan. The formulary contains tiers based on a drug's preferred or non-preferred status, and specialty or non-specialty status.

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefits Manager, CVS Caremark® (sometimes referred to as "PBM" or "Caremark"), including formulary management. The PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the Five (5) Tier Exchange Formulary – Aetna ("EXCH-Aetna") formulary. The PBM's tiered formulary structure designates drugs as generic or brand, designates brand drugs as preferred or non-preferred, and designates drugs as specialty or non-specialty. Aetna further designates generic drugs as preferred and non-preferred and assigns cost share ranges to each tier. The Certificate of Coverage and Schedule of Benefits filed and approved by the state of Virginia support a variable range of member cost shares. There is no separate cost-share structure for MH/SUD drugs and M/S drugs. In accordance with 29 C.F.R. § 146.136(c)(3)(iii)(A), applicable to multi-tiered prescription benefits, the different levels of financial requirements are applied to different tiers of prescription benefits based on reasonable factors determined in accordance with rules relating to requirements for NQTLs and without regard to whether a drug is generally prescribed with respect to M/S benefits or MH/SUD benefits. The tiered benefit and cost-share design encourages generic utilization and lower pharmacy cost through copay differentials and encourages behaviors that will ultimately lead to appropriate utilization of cost-effective generics and preferred brand drugs.

In the prescription drug benefit classification, the following materials describe formulary design/tiering:

1. PLAN DOCUMENTS

Certificate of Coverage: HPOL 04 SERFF# AETN-133977008

Covered services are based on the drugs listed in the **drug guide**. We exclude **prescription** drugs not in the **drug guide** unless we approve a medical exception. If it is **medically necessary** for you to use a **prescription** drug that is not in this **drug guide**, you or your **provider** must

request a medical exception. See the *Requesting a medical exception* section for more information. We will notify you in writing 30 days prior to a change to the **drug guide** that results in a **prescription** drug moving to a higher cost-sharing tier.

The pharmacy may substitute a **generic prescription drug** for a **brand-name prescription drug**. Your cost share may be less if you use a generic drug when it is available.

Where your schedule of benefits fits in
The schedule of benefits shows any out-of-pocket costs you are responsible for when you receive **covered services** and any benefit limitations that apply to your policy. It also shows any **maximum out-of-pocket limits** that apply. We will notify you that you have met your **maximum out-of-pocket limit** no later than 30 days after we have paid enough claims to make that determination. You will not be required to pay a cost share for eligible **covered services** for the rest of the plan year. Any amounts over your **maximum out-of-pocket limit** will be promptly refunded to you.

Schedule of Benefits: SOB 04 SERFF# AETN- 133977008

The Schedule of Benefits provides the member cost shares for covered services as outlined in the Certificate of Coverage.

2. DRUG GUIDE

The drug guide indicates the tier of covered drugs. It also provides definitions and other information for members. The most current version is publicly available at: Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers. The most current version is publicly available at: Aetna Provider Manual

4. POLICIES AND PROCEDURES

The following materials describe formulary design/tiering:

Document #	Title	Description
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
CPANDT-0002	CVS Caremark® National Pharmacy and	This policy defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T)

	Therapeutics (P&T) Committee	Committee as well as requirements regarding conflicts of interest, meeting administration, and formulary decisions.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the file attached below contains all MH/SUD and M/S prescription drugs covered under the prescription drug benefit. These drugs are therefore subject to formulary design/tiering.

VIRGINIA: AETNA – EXCHANGE FORMULARY 2025	
EXCH Formulary Tiering 2025.xlsx	
Benefit classifications to which NQTL applies: a Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs labeled as Medical/Surgical in the attached Drug File	▪ Prescription Drugs labeled as MH or SUD in the attached Drug File

Step 2:Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

Tier 1 Drug Placement

A drug's placement in **Tier 1** indicates that it is a generic medication. Generic drugs are medications that have the same active ingredients, strength, and effectiveness as brand-name drugs, but they usually cost less. They are approved by the FDA and work the same way in the body, but they do not carry the brand name. This Tier 1 generic strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Generic Status	✓	✓

Generic Status means, drugs/medications that have the same active ingredients, strength, and effectiveness as brand-name drugs, but they usually cost less. They are approved by the FDA and work the same way in the body, but they do not carry the brand name. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Generic Status
- **Sources:**
  - Medi-Span Drug Database Brand Generic Reference

Additionally, generic drugs are placed on Tier 1 (as preferred generic) or Tier 3 (non-preferred generic). Indication of preferred and non-preferred generic status means the generic drug costs less (preferred) or more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 2 Drug Placement

A drug's placement in **Tier 2** indicates that it is considered a preferred brand-name medication. This designation is based on Caremark's preferred tier strategy, which evaluates brand/generic availability, and cost-effectiveness. The strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Financial Net Cost	✓	✓

Financial Net Cost means: The estimated total cost of a drug to the plan, calculated after accounting for wholesale acquisition cost (WAC), negotiated rebates, price concessions, or other financial incentives. Net cost is used as a financial factor as part of the assessment of a brand-name drug for inclusion as a preferred brand (Tier 2) on the formulary. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Pricing analyzed using a standard cost-model based on the drug's WAC minus rebates or another uniform pricing formula, applied consistently across all drugs within a therapeutic class.
- **Sources**
  - Medi-Span Drug Database Brand Generic Reference and WAC
  - Manufacturer Agreements (Applicable rebates)
  - Rx Claim PBM Database (WAC and script utilization by formulary)
  - FDA labeling

Tier 3 Drug Placement

A drug's placement in **Tier 3** indicates that it is a non-preferred brand. This Tier 3 strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Financial Net Cost	✓	✓

Financial Net Cost means: The estimated total cost of a drug to the plan, calculated after accounting for wholesale acquisition cost (WAC), negotiated rebates, price concessions, or other financial incentives. Net cost is used as a financial factor as part of the assessment of a brand-name drug for inclusion as a preferred brand (Tier 2) on the formulary. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Pricing analyzed using a standard cost-model based on the drug's WAC minus rebates or another uniform pricing formula, applied consistently across all drugs within a therapeutic class.
- **Sources**
  - Medi-Span Drug Database Brand Generic Reference and WAC
  - Manufacturer Agreements (Applicable rebates)
  - Rx Claim PBM Database (WAC and script utilization by formulary)
  - FDA labeling

Additionally, certain generic drugs are placed on Tier 3 (as non-preferred generic). which means the generic drug costs more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined to be non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 4 and Tier 5 Drug Placement

Factor	Applicable to M/S	Applicable to MH/SUD
Specialty Drug Status	✓	✓

Specialty drug designation is based on review and recommendation by a cross-functional clinical committee that evaluates clinical complexity, cost, and other relevant criteria. MH/SUD and M/S drugs designated as specialty medications are placed on Tiers 4 and 5, based upon whether the drug is identified as a preferred or non-preferred drug, as defined above. Drugs that are designated as specialty preferred are placed in Tier 4, and drugs designated as specialty non-preferred are placed in Tier 5. This strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

As set forth in Step 2, the factors used to determine a drug's tier placement are 1) generic status; 2) net cost; 3) specialty drug status. This section explains how these factors are used to determine drug tier placement. Based upon these factors, Aetna's PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the 5 tier EXCH-Aetna formulary. The PBM's tiered formulary structure designates drugs as generic or brand, designates brand drugs as preferred or non-preferred, and designates drugs as specialty or non-specialty. Aetna further designates generic drugs as preferred and non-preferred, and assigns cost share ranges to each tier. The determination of which drugs are placed into each tier is based upon the same factors, strategies, and processes, and is evaluated consistently, regardless of therapeutic category, and without regard to whether the drug is used to treat M/S or MH/SUD conditions.

In making formulary decisions, Caremark considers clinical, financial, and market factors. All formulary decisions are approved by the CVS Caremark National Pharmacy & Therapeutics (P&T) Committee, which is an independent, external body. The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the formulary tiering process:

- The Formulary Administration team is comprised of analysts and pharmacists and oversees the standard template formulary development and management. The team monitors new drug databases, reviews the sources and evidentiary standards, conducts the drug evaluations, and provides information about placement on the formulary and tier assignment.
- The Formulary Review Committee (FRC) is comprised of individuals with expertise in pharmacy benefit management. This committee makes final recommendations for drug inclusions and tier placements for the CVS Caremark National Pharmacy and Therapeutics Committee's (P&T Committee) review and approval for template formularies. The FRC meets a minimum of 10 times per year and on an ad hoc basis as needed, to discuss and review proposals for formulary changes.
- The Clinical Formulary team is comprised of analysts and pharmacists and develops drug information documents. These documents are shared with other teams and experts involved in formulary development and the P&T Committee.
- The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds

and/or academic expertise regarding prescription drugs, and it meets at least quarterly. The committee's role with respect to tiering determinations is advisory in nature.

The FRC and P&T Committee members include experts from a variety of clinical fields including behavioral health, as well as experts in pharmacy benefits management.

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CVS Caremark Personnel Titles, Credentials and Committees Composition

The **Formulary Administration Department** oversees the standard template formulary development and management.

Job Title, Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Lead Director, Pharmacist
Sr Managers, Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Formulary Department** writes drug information materials in support of the P&T Committee.

Job Title, Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Lead Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analysts

The **Formulary Review Committee (FRC)** makes business recommendations. It includes individuals with expertise in pharmacy benefit management.

Voting Members Job Title, Credential	Business Unit
Lead Director Chairperson	Trade Relations
VP, Pharmacist	Product Development - Sales
Executive Director, MBA	Finance
Executive Director, MBA	Trade Relations
AVP, Pharmacist	Medical Affairs
Sr Manager, Pharmacist	Clinical Client Operations

The **P&T Committee**, an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs.

Voting Members, Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Internal Medicine
MD – Cardiology	MD – Infectious Disease

MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
PharmD – Gerontology	MD – Adult Psychiatry
MD – Gerontology	MD – Pediatric Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Advocate

Tier 1 Drug Placement

1. The generic status factor is used to determine tier placement as follows: A licensed PBM pharmacist reviews the drug specific source to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for Tier 1 placement. The drug database with Medi-Span information is queried by a licensed PBM pharmacist to locate the drug-specific Brand Generic Reference information section.

2. If the Brand Generic Reference is equal to "Y-GENERIC"; then the drug is generic is placed on Tier 1.

The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

The following scenario is assessed to identify if the standard is met. If **the scenario** applies to the drug, then the drug is considered a generic drug: a licensed PBM pharmacist reviews the Brand Generic Reference information to determine whether a drug qualifies as generic for Tier 1 placement. This scenario is consistently evaluated across all drug classes without regard to whether the drug is used to treat MH/SUD or M/S conditions.

Additionally, generic drugs are placed on Tier 1 (as preferred generic) or Tier 3 (non-preferred generic). Indication of preferred and non-preferred generic status means the generic drug costs less (preferred) or more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy are applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 2 Drug Placement

The Financial Net Cost factor is used to determine tier placement as follows: Individuals with expertise in pharmacy benefit management review the drug and disease-specific sources to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for Tier 2 preferred brand status. Therapeutic classes include brand and/or generic drugs that treat

similar conditions and compete with each other in the market. Net costs are calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.

The therapeutic categories are reviewed annually to evaluate any future changes based on new market entrants, changes in pricing or rebate contracts. Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable clinical and economic balance. Market factors such as supply chain durability (e.g., drug shortages) are also considered when no brands are preferred or only generics are covered. The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

Therapeutic Class Evaluation: Drugs are grouped and reviewed by therapeutic class. The therapeutic class framework allows for the identification of the product that offers the best overall value considering both clinical effectiveness, market conditions and net cost.

Net Cost Modeling: Net cost is calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.

Any of the following modeling scenarios could result in preferred brand designation:

1. Lowest net cost among brands (rebate-adjusted)
    - The brand offers the lowest WAC minus rebate among all brands in the class.
    - Generic alternatives may or may not exist within a therapeutic class.

2. Broader Indications
    - The brand has unique or broader indications relative to other brands in the drug category.
    - Net cost is competitive—even if not the lowest relative to other brands

3. Limited generic availability
    - A generic version exists but it may have supply constraints in the market which may require coverage of the brand
    - The brand is temporarily maintained as covered on formulary which may be in the preferred tier or non-preferred brand tier while the shortage of the generic version persists.

These scenarios are consistently evaluated across all drug classes without regard to whether the drug is used to treat MH/SUD or M/S conditions.

Tier 3 Drug Placement

The Financial Net Cost factor is used to determine tier placement as follows: Individuals with expertise in pharmacy benefit management review the drug and disease-specific sources to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for

Tier 2 preferred brand status, as mentioned above. Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable balance of clinical and economic value, as well as market factors such as supply chain durability (e.g., drug shortages) across the therapeutic class, either because no brands are preferred or only generics are covered. Non-preferred brand content is derived from the remaining products that are not placed on Tier 1 or 2. The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

The following scenario is assessed to identify if the standard is met. If the scenario applies to the brand drug, then the drug is assigned to Tier 3.

Net Cost Evaluation

- Products Net cost is calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.
- Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable balance of clinical and economic value
- Tier 3 non-preferred brand content is derived from remaining products that are not placed on Tier 1 or 2, which do not demonstrate the most favorable economic value.

This scenario is consistently evaluated across all drug classes without regard to whether the drug used to treat MH/SUD or M/S conditions.

Additionally, certain generic drugs are placed on Tier 3 (non-preferred generic). Indication of non-preferred generic status means the generic drug costs less more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

<u>Tier 4 and 5 Drug Placement</u>

Drug placement on Tiers 4 and 5 indicate that the drug is designated as a specialty drug. Specialty drug designation is based on review and recommendation by a cross-functional clinical committee that evaluates clinical complexity, cost, and other relevant criteria. Caremark adopts specialty drug status in connection with its standard formulary development process, and this designation is reflected in Aetna's formularies. MH/SUD and M/S drugs designated as specialty medications are placed on Tiers 4 and 5, based upon whether the drug is identified as a preferred or non-preferred drug, as defined above. Drugs that are designated as specialty and preferred are placed in Tier 4, and drugs designated as specialty and non-preferred are placed in Tier 5.

The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated, designated as specialty drug, and placed on Tiers 4 and 5. This

evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Relationship, ordering and weighting of multiple factors:

The factors listed above are interrelated, but apply to distinct formulary tiers, including Tiers 1-5 of the standard EXCH-Aetna formulary. No factor is weighted more heavily than the other, and all operate together to ensure employment of a formulary design that encourages appropriate utilization of cost-effective drugs. The determination of which drugs are placed into each tier is based upon the same factors, strategies, and processes, and is evaluated consistently, regardless of therapeutic category, and without regard to whether the drug is used to treat M/S or MH/SUD conditions.

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering with respect to M/S drugs in the prescription drug benefit classification. CVS Caremark materials related to formulary design/tiering include:

Document #	Title	Description
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
CPANDT-0002	CVS Caremark National Pharmacy and Therapeutics (P&T) Committee	This policy defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee as well as requirements regarding Conflict of Interest, meeting administration, and formulary decisions.

The determination of which drugs are placed into each tier is based upon the same strategies and processes regardless of therapeutic category. Factors and evidentiary standards are applied

consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions.

As written, the **Formulary Development and Management at CVS Caremark** document describes the underlying principles of the CVS Caremark formulary management and development process, and provides information about the groups involved in decision-making and oversight. There is no distinction between processes and committees used for M/S and MH/SUD drugs. The process for the development and management of the formulary, including committee members and meetings, is the same regardless of drug category.

As written, **Policy CPANDT-0002 CVS Caremark National Pharmacy and Therapeutics (P&T) Committee** defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee, including membership, meeting administration and formulary decisions. All members of the P&T Committee are independent contractors that are clinical experts from a variety of medical specialties that include both M/S and MH/SUD practitioners. Pursuant to this policy, the CVS Caremark National P&T Committee will review and approve drugs for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the formulary. Further, the CVS Caremark National P&T Committee will ensure that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states from a formulary and utilization management perspective. This policy applies generally to both M/S and MH/SUD drugs.

Additionally, the following provides a demonstration of how factors are applies to MH/SUD and M/S drugs for various tiers. The specific drugs in the following section were selected for illustrative purposes.

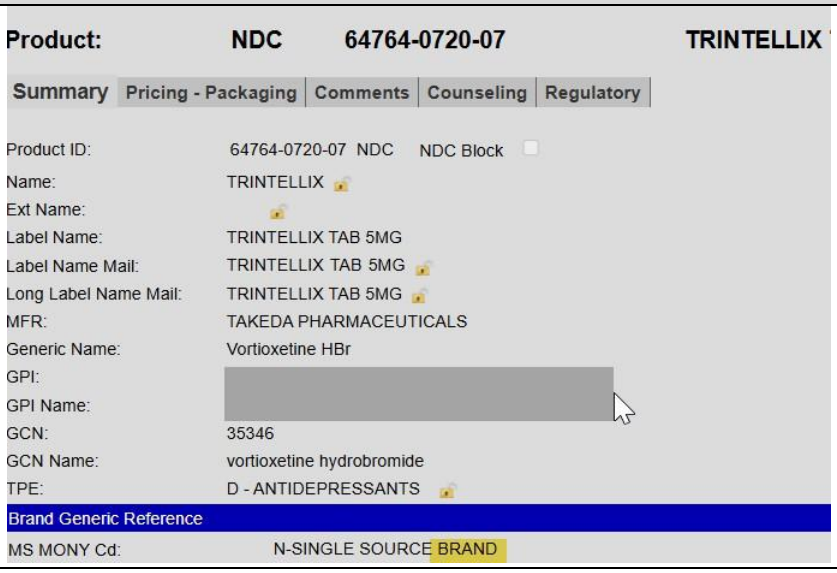
Tier 1 Drug Placement

The demonstration below illustrates how the factors are applied to MH/SUD and M/S drugs.

Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Captopril **MH/SUD:** No **Drug Group Description:** Antihypertensives		**Tier 1** Source confirms GENERIC This generic drug is placed in Tier 1.

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Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Duloxetine **MH/SUD:** Yes - MH **Drug Group Description:** Antidepressants		**Tier 1** Source confirms GENERIC This generic drug is placed in Tier 1.
Drug Name: Vivjoa **MH/SUD:** No **Drug Group Description:** Antifungals		Source confirms BRAND This brand drug is NOT placed in Tier 1.

Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Trintellix **MH/SUD:** Yes **Drug Group Description:** Antidepressants		Source confirms BRAND This brand drug is NOT placed in Tier 1.

Tier 2 Drug Placement

The following section illustrates how the preferred brand designation methodology is applied in practice using two representative drugs—one used to treat a MH/SUD condition, and one used to treat a M/S condition. These examples demonstrate the consistent application of the preferred brand designation criteria across therapeutic classes.

Note: While the methodology to determine brand coverage is applied consistently across all drug categories, the specific modeling scenarios may vary based on clinical and/or market dynamics—such as generic availability, market competition, or clinical indications. For example, many MH/SUD drug classes have high generic market penetration—often exceeding 90%—which significantly reduces the likelihood that a brand-name MH/SUD drug in that class will be selected for preferred status. In contrast, some MED/SURG drugs may not face the same degree of generic competition or may offer unique clinical attributes that justify a preferred designation despite higher cost. Accordingly, the differences in modeling scenarios reflect underlying market conditions and therapeutic class characteristics, not inconsistency in how the tiering methodology is applied.

The demonstration below illustrates how the factors are applied in practice to MH/SUD and M/S drugs.

Drug Name Qelbree
MH/SUD Yes
Category Attention Deficit Hyperactivity Disorder Non-Stimulants

Applicable Modeling Scenario # 1

ADHD Non-Stimulants	
BRAND	**Generic**
not available	clonidine ER
Intuniv	guanfacine ER
Onyda XR	*not available*
Qelbree	*not available*
Strattera	atomoxetine

- **Generic Alternatives**: atomoxetine, clonidine ER, guanfacine ER
- **Generic market share**: > 90% as measured by claims volume
- **Other brands**: Intuniv, Onyda XR, Strattera
- **WAC** derived from Medi-Span drug database:
  - Qelbree $520 (30-day supply)
  - Intuniv $370 (30-day supply) (Generic Available)
  - Onyda XR $480 (30-day supply)
  - Strattera $505 (30-day supply) (Generic Available)
- Any applicable rebates derived from manufacturer contracts
- Qelbree net costs are less by 9% to 16% compared to other branded products when the rebates are applied
- Generic costs are $52 for a 30-day supply and are less than preferred branded products (net of rebates) by a factor of 8 times

Tier Designation: Based on clinical factors, net costs of all products in the category, and market dynamics, Qelbree tier placement is preferred at the lowest branded tier, with all other brands at a higher tier or not covered. Generics are still the most preferred (Tier 1) agents.

Drug Name Austedo
MH/SUD No
Category Movement Disorders Huntington's Disease/Tardive Dyskinesia

Applicable Modeling Scenario: 2

Movement Disorders	
BRAND	**Generic**
Austedo	*not available*
Ingrezza	*not available*
Xenazine	tetrabenazine

- **Generic Alternatives**: tetrabenazine
- **Generic market share**: approximately 10% as measured by claims volume
- **Other brands**: Ingrezza, Xenazine
- **WAC** derived from Medi-Span drug database:
  - Austedo $7,960 (30-day supply)
  - Ingrezza $7,999 (30-day supply)
  - Xenazine $22,788 (30-day supply) (Generic Available)
- Applicable rebates derived from manufacturer contracts
- Based on WAC less rebates to derive lowest net cost, Ingrezza is the least expensive brand, with the net cost of Austedo 7% to 12% higher. Branded Xenazine has a net cost approximately 3.5 times higher (350%) than either of the other brand products.

- Generic costs for a 30-day supply of tetrabenazine are $4,715 and are less than branded products (net of rebates) by 27% to 30%
- Note, generic Tetrabenazine, which treats Huntington's Disease only, requires use multiple times daily vs. branded Austedo which treats both Huntington's Disease and Tardive Dyskinesia. Ingrezza only treats Tardive Dyskinesia.

Tier Designation: Austedo and Ingrezza are preferred at the lowest branded tier. Ingrezza is the lowest-net product in the class but only treats Tardive Dyskinesia; Austedo treats both Huntington's Disease and Tardive Dyskinesia. Factoring in the clinical profiles with the economic factors, both Ingrezza and Austedo are placed in a preferred brand tier, with Xenazine, which has a generic alternative, not covered.

Tier 3 Drug Placement

The demonstration below illustrates how the factors are applied in practice.

Drug Name Rexulti
MH/SUD Yes
Category Antipsychotics – Atypical

Applicable Modeling Scenario # 1

- **Generic Alternatives**: aripiprazole, asenapine, clozapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone
- **Generic market share**: 86% as measured by claims volume
- **Other brands**: Caplyta, Rexulti, Vraylar
- **WAC** derived from Medi-Span drug database:
  - Caplyta $1,672 (30-day supply)
  - Rexulti $1,485 (30-day supply)
  - Vraylar $1,444 (30-day supply)
- Any applicable rebates derived from manufacturer contracts
- All branded products with generic alternatives excluded
- Vraylar net costs are less by 10% to 21% compared to other branded products when the rebates are applied
- Rexulti net costs are less by 12% compared to other branded products when the rebates are applied
- Generic costs are $17 for a 30-day supply and are less than branded products (net of rebates) by a factor of 60 times

Antipsychotics - Atypical	
BRAND	**Generic**
Caplyta	*not available*
Rexulti	*not available*
Vraylar	*not available*
Abilify	aripiprazole
Versacloz	clozapine
Latuda	lurasidone
Zyprexa	olanzapine
Invega	paliperidone
Seroquel	quetiapine
Fanapt	*not available*
Risperdal	risperidone
Clozaril	clozapine
Secuado	*not available*
Saphris	asenapine
Opipza	*not available*
Geodon	ziprasidone

Tier Designation: Based on clinical factors, net costs of all products in the category, and market dynamics, Rexulti placement is Tier 3.

Summary

The written materials discussed herein, pertaining to formulary design/tiering for MH/SUD and M/S drugs, all apply equally to MH/SUD and M/S drugs, and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2. No separate policies, procedures or documents exist with respect to formulary design and tiering for MH/SUD drugs as compared to

M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply formulary design/tiering with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply formulary design/tiering with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering with respect to M/S drugs. A review was conducted to evaluate the formulary status and tier assignment of MH/SUD and M/S drugs.

Testing Methodology

The input drug coverage extract file was processed and analyzed as follows:

- Using the Medi-Span Generic Product Identifier (GPI) therapeutic classification system, drugs with the same GPI code, brand/generic code, dosage form & strength, name, and route of administration were counted as one.
- Drugs were grouped into MH, SUD and M/S drug types, organized into formulary tiers, counted, and the totals were used to calculate the percentages of drugs in each tier by type.
- Drugs were grouped by preferred tiers, counted, and the totals were used to calculate the percentages with this preferred tier drug status.

To calculate the percent of drug type in each tier, the formula used is (X/Y)*100, where:

- X = the count of drugs of each type by tier
- Y = the total count of that drug type in the formulary

To calculate the percent of drug type with preferred formulary status, the formula used is [(A+B+C+…)/Y]*100, where:

- A, B, C, ... = the count of drugs of each type in preferred tiers
- Y = the total count of that drug type in the formulary

Results

The output formulary file attached in Step1, part 2 contains the drugs, formulary status, and tier assignment for the EXCH-Aetna Formulary:

Formulary Tier Descriptions

- Tier 1 = Preferred Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands & Generics
- Tier 4 = Preferred Specialty
- Tier 5 = Non-Preferred Specialty

Formulary Tiering by Drug Type

Aetna - Exchange Formulary 2025

Drug Type	Results												
MED/SURG	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	114	1674	562	620	0	40	0	0	0	0	0	3010	78.1%
	3.8%	55.6%	18.7%	20.6%	0.0%	1.3%	0.0%	0.0%	0.0%	0.0%	0.0%		
MH	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	4	413	11	163	0	1	0	0	0	0	0	592	72.3%
	0.7%	69.8%	1.9%	27.5%	0.0%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%		
SUD	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	14	80	2	4	0	0	0	0	0	0	0	100	96.0%
	14.0%	80.0%	2.0%	4.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		

In operation, the analysis and testing of the tiers shows that a higher percentage of MH/SUD drugs are placed within the lowest, preferred tier (Tier 1) than M/S drugs, revealing that the factors and the sources are not used differently or more stringently with respect to MH/SUD compared to M/S drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs. Based upon review of the data and information addressed herein, Aetna may conclude that, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying formulary design/tiering with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying formulary design/tiering with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of its prescription drug benefit to its PBM, including formulary management. In the prescription drug benefit classification, a formulary is the list of generic and brand medications covered by a health benefit plan. The formulary contains tiers based on a drug's preferred or non-preferred status, and specialty or non-specialty status. The PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the 5 Tier EXCH-Aetna formulary, and Aetna assigns cost share ranges to each tier. The Certificate of Coverage and Schedule of Benefits filed and approved by the state of Virginia support a variable range of member cost shares. There is no separate cost-share structure for MH/SUD drugs and M/S drugs.

Step 2 identified the factors that are used to design and apply formulary design/tiering to M/S and MH/SUD drugs, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of formulary design/tiering; there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, as written, to M/S and MH/SUD drugs, and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to formulary design/tiering in a comparable manner and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that formulary design/tiering is designed and applied in a comparable manner to MH/SUD and M/S drugs.

More specifically, as demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining formulary design/tiering for M/S and MH/SUD drugs. An as-written comparative analysis shows that no separate policies or procedures exist with respect to formulary design/tiering for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs, and the factors, sources and evidentiary standards are used in a comparable and no more stringent manner to determine formulary tier placement for MH/SUD and M/S drugs. This information and review demonstrate that, as written, formulary design/tiering is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

In addition, as demonstrated in **Step 5**, in operation, formulary design/tiering is applied in a comparable manner for both M/S and MH/SUD drugs. Testing of the formulary tiers and preferred drug composition shows that overall, a higher percentage of MH/SUD drugs are placed within the preferred, lowest cost tier (Tier 1) than M/S drugs. Accordingly, the factors, evidentiary standards and sources are not used differently or more stringently with respect to MH/SUD compared to M/S drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying formulary design/tiering to M/S drugs. Moreover, in accordance with 29 C.F.R. § 146.136(c)(3)(iii)(A), applicable to multi-tiered prescription benefits, Aetna has demonstrated that different levels of financial requirements are applied to different tiers of prescription benefits based on reasonable factors determined in accordance with rules relating to requirements for NQTLs and without regard to whether a drug is generally prescribed with respect to M/S benefits or with respect to MH/SUD benefits.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Aetna Health Plan Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Health Plan Pharmacy (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: PRIOR AUTHORIZATION
VIRGINIA: EXCHANGE FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Prior Authorization

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® ("Caremark" or "PBM"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Prior authorization (hereinafter sometimes "PA") refers to a process that requires the prescribed use of a drug to be evaluated against a predetermined set of objective criteria before the prescription can be filled under a benefit plan. Prior authorization criteria documents define the circumstances under which a prior authorization medication should be paid under a prescription benefit plan. Prior authorization of prescription drugs is conducted by the Caremark Prior Authorization Department using pre-established medical necessity guidelines developed by Caremark.

In the prescription drug benefit classification, the following materials describe prior authorization:

1. PLAN DOCUMENTS

Certificate of Coverage: HPOL 04 SERFF# AETN-133977008

For certain drugs covered under your medical plan or **prescription** drug plan, your **provider** needs to get approval from us before we will cover the drug. The requirement for getting approval in advance guides appropriate use of certain drugs and makes sure they are **medically necessary**.

Step therapy is a type of **precertification** where you must try one or more prerequisite drugs before a step therapy drug is covered. A 'prerequisite' is something that is required before something else. Prerequisite drugs are FDA-approved, may cost less, and treat the same condition. If you don't try the prerequisite drugs first, the step therapy drug may not be covered.

Contact us or go online to get the most up-to-date **precertification** requirements and list of step therapy drugs.

Requesting a medical exception
Sometimes you or your **provider** may ask for a medical exception to get coverage for drugs that are not covered or for brand-name or specialty **prescription** drugs for which health care services are denied through **precertification** or step therapy.

You, someone who represents you, or your **provider** can contact us. You will need to provide us with the required clinical documentation. Any exception granted is based upon an individual and is a case by case decision. For directions on how you can submit a request for a review:
Call the toll-free number on your ID card
Go online at https://www.aetnacvshealth.com
Submit the request in writing to:

CVS Health
ATTN: Aetna PA
1300 E Campbell Road
Richardson, TX 75081

2. DRUG GUIDE

The Drug Guide provides important information for members pertaining to prior authorization, including the medications requiring precertification. This list is subject to change. The most current version is publicly available at: Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information pertaining to prior authorization. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies describe prior authorization:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide attached below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: EXCHANGE FORMULARY 2025 DRUG GUIDE
2025_Aetna_Health _Exchange_Plan.pdf
Benefit classifications to which NQTL applies: ✔ Prescription Drug

M/S services NQTL applies to:	MH/SUD services NQTL applies to:
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) including a drug or drug class in prior authorization programs; and b) development of coverage criteria. Aetna's PBM develops standard formularies and assigns utilization management designations such as prior authorization, step therapy and quantity limits based on clinical, safety and cost-effectiveness factors supported by nationally recognized evidence and guidelines.

(a) Factors for including a drug or drug class in prior authorization programs.

The determination of which drugs are subject to utilization management, including prior authorization, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including prior authorization, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in prior authorization programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓

Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2) Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
    - FDA drug approvals and databases with drug specific product information
    - Clinical Practice Guidelines
    - Drug information databases/Compendia
    - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
    - FDA Drug-specific product label
    - FDA Online Label Repository
    - FDA Drug Safety-related Labeling Changes (SrLC)
    - FDA Drug Trial Snapshot
    - Disease specific Clinical Practice Guideline Protocols
    - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
    - AHFS Drug Information and/or Lexi-Drugs
    - Micromedex DRUGDEX® (IBM Watson Health)
    - Clinical Pharmacology
    - Medline (PubMed)
    - Up To Date drug database
    - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
    - Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
    - FDA drug approvals and databases with drug specific product information
    - Clinical Practice Guidelines

  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards**:
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
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- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report

  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)
  - Healthcare.gov
  - NCQA.org
  - URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia

  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

(b) Factors for the development of coverage criteria

The development of coverage criteria for drugs that require prior authorization is based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective

because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2) Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)

- FDA Drug Trial Snapshot
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Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence

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Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards**:
  - FDA drug approvals and databases with drug specific product information
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  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
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  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
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  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has

potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov

- Individual state regulations sites
- Health and Human Services (HHS.gov)
- Healthcare.gov
- NCQA.org
- URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization

- Manufacturer Agreements or Rebate Contracts
- Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including prior authorization, and the development of coverage criteria for drugs that require prior authorization, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require prior authorization for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in prior authorization programs and upon which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including prior authorization, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs. The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential

VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy
Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a Caremark Medical Director, and by external clinical experts whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst

External Clinical Experts

- The P&T Committee reviews and approves the clinical criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to M/S drugs in the prescription drug benefit classifications. Caremark policies related to prior authorization include:

Document #	Title	Description

DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark® Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure document the requirements for the prior authorization process for plans subject to Virginia (IN) state laws.

INCLUDING A DRUG OR DRUG CLASS IN PRIOR AUTHORIZATION PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in prior authorization programs and upon which development of coverage criteria is based are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in prior authorization programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (prior authorization, step therapy, quantity limits) to a drug or drug class are applied consistently across

all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary source, must support the coverage conditions of the prior authorization requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard CVS Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply prior authorization to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.

- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The type(s) of NQTL (prior authorization, step therapy and/or quantity limits) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.
- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.
- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC

standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs (including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION- PRIOR AUTHORIZATION DESIGN PROCESS
DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's (PA, ST, QL) development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to

the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.

v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.

vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustration only, and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil) **MH/SUD:** Yes **M/S:** No **Therapeutic Category:** Stimulants (Miscellaneous)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • Narcolepsy
	  • Shift Work Disorder (SWD)

Step 3	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established

in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective.
  Accessed 06-09-25
- Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil).
  Accessed 06-10-25

- Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy.
- Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
  Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

	Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil). Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 **Off-label Prescribing Patterns**. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. ◦ CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.
Step 5	The sources that were used and documented for armodafinil include: ◦ Prescribing information for armodafinil (Nuvigil) ◦ Drug information Databases and compendia ▪ Lexicomp AHFS DI ▪ Micromedex ◦ Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.
	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification
	  • Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy.
	  • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil.
	• Reason for Type of NQTL
	  • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy.
	  • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil):
	  ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days
	  ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days

	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION

Caremark performs utilization management on Aetna's behalf. Its policies are used to determine operational aspects of prior authorization. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting prior authorization for both M/S and MH/SUD drugs. This policy documents the requirements for the prior authorization process for plans subject to Virginia (VA) laws. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.

i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.

i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded

to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:
    a. Urgent PA Reviews will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.
2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.
    a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
    b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    c. Notification will be provided within 24 hours of making the adverse determination.
3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:
    a. Urgent step therapy requests will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;

ii. The reason(s) for the Adverse Determination;

iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;

iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;

v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;

vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.

vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs require prior authorization, the development of coverage criteria, and the process of conducting prior authorization, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for

development of the same. No separate policies or procedures exist with respect to prior authorization for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply prior authorization with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply prior authorization with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to M/S drugs.

As discussed in Step 4 above, the application of prior authorization within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for prior authorization—including submission requirements, review timelines, clinical documentation standards, and appeal processes—are identical across both benefit categories. The operation of the prior authorization process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation analysis is conducted by reviewing the following:

- Prior Authorization Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – PRIOR AUTHORIZATIONS

Evaluation of approval/denial rates for M/S and MH/SUD prior authorization requests is one measure that can evaluate whether prior authorization is applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects prior authorization decisions for MH/SUD and M/S drugs on the **Aetna Exchange Formulary for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied.

Approval/Denial Rates – Prior Authorizations			
VIRGINIA - Aetna Exchange Formulary – 2025			
Drug Type	MED/SURG	MH	SUD
Total Requests	1,807	69	6
Total Approvals	1,282	56	6
Total Denials	525	13	-
Approval Percent	70.9%	81.2%	100.0%
Denial Percent	29.1%	18.8%	0.0%
Average TAT in Days	0.315	0.089	0.002

This data reflects that overall, **81.2%** of prior authorizations for MH drugs were approved, and **70.9%** of M/S drugs were approved. **100%** of SUD prior authorization requests were approved. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs was less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying prior authorization to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its PBM, Caremark, audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or M/S condition.

- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In summary, based upon review of the data and information addressed herein, Aetna concludes that the processes, strategies, evidentiary standards or other factors used in designing and applying prior authorization with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying prior authorization with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its Pharmacy Benefit Manager, CVS Caremark®, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Prior authorization refers to a process that requires the prescribed use of a drug to be evaluated against a predetermined set of objective criteria before the prescription can be filled under a benefit plan. Prior authorization criteria documents define the circumstances under which a prior authorization medication should be paid under a prescription benefit plan.

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to prior authorization, and the development of coverage criteria for drugs that require prior authorization, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of prior authorization. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to prior authorization and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to prior authorization in a comparable manner, and the MH/SUD drugs to which prior authorization applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The

comparative analysis conducted above demonstrates that prior authorization is designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to prior authorization, the development of coverage criteria for drugs that require prior authorization, and the process of conducting prior authorization. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply prior authorization. That analysis shows that no separate policies or procedures exist with respect to prior authorization for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying prior authorization in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. CVS Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, prior authorization is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, prior authorization is applied in a comparable manner for both M/S and MH/SUD drugs. The application of prior authorization within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs. The operational procedures for prior authorization are identical across both benefit categories. The operation of the prior authorization process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of prior authorization approval and denial rates, which demonstrated lower rates of prior authorization denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating prior authorization coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases

demonstrated that the process for reviews was consistent across all prior authorization requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying prior authorization to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan(Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: QUANTITY LIMITS
VIRGINIA: EXCHANGE FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Quantity Limits

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® (hereinafter "PBM" or "Caremark"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Quantity limits (hereinafter sometimes "QL") refers to a limitation that establishes a maximum quantity of a drug that is covered over a specified period of time. In the prescription drug benefit classification, the following materials describe quantity limits:

1. PLAN DOCUMENTS

Certificate of Coverage: HPOL 04 SERFF# AETN-133977008

Prescription drugs covered under this plan are subject to misuse, waste or abuse utilization review by us, your **[provider]** or your network pharmacy. The outcome of the review may include:

- Limiting coverage of a drug to one prescribing **[provider]** or one network pharmacy
- Quantity, dosage or day supply limits
- Requiring a partial fill or denial of coverage]

2. DRUG GUIDE

The Drug Guide provides important information for members pertaining to quantity limits, including the drugs subject to quantity limits and information about exceptions to quantity limit requirements. The most current version is publicly available at:

Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

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3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information about drugs subject to quantity limits and exceptions to quantity limit requirements. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. They also describe the medical exception clinical coverage criteria for drugs subject to quantity limits. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies pertain to quantity limits:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management NQTLs (prior authorization, quantity limits, and step therapy) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.

at CVS Caremark®		
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process, including as applicable for prior authorization requests for exceptions to quantity limits, for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: EXCHANGE FORMULARY 2025 DRUG GUIDE 2025_Aetna_Health_Exchange_Plan.pdf	
Benefit classifications to which NQTL applies: ✔ **Prescription Drug**	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following section identifies and defines the factors, evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) quantity limit programs; and b) development of coverage criteria. Aetna's PBM, Caremark, maintains standard utilization management (UM) policies that include quantity limits and clinical criteria developed based on nationally recognized clinical guidelines, FDA labeling, and evidence-based literature.

a. Factors for including a drug or drug class in quantity limits programs.

The determination of which drugs are subject to utilization management, including quantity limits, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including quantity limits, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in quantity limits programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Evidence-based Uses and Clinical Efficacy	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Cost Effectiveness	✓	✓

Evidence-based Uses and Clinical Efficacy means: 1) Potentially unsafe and ineffective dose escalation - Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule; Drug or drug class has potential for being prescribed for periods of time exceeding the recommended duration of therapy or when therapy ceases to provide benefit; Drug or drug class has no evidence or data regarding efficacy at doses above the FDA approved limit; Drug or drug class has evidence that increasing the dose past the FDA approved limits does not provide improved efficacy. 2) Dose Optimization - Drug or drug class has evidence that the number of dosage units can be reduced by using a higher strength formulation of the drug without compromising efficacy. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon .The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, including drugs that may be equally efficacious and less costly; 2) High utilization - Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits. An NQTL may be applied to ensure dosing follows the FDA approved limit and is in alignment with the FDA labeled indication(s).The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

b. Factors for the development of coverage criteria

The development of coverage criteria for drugs subject to quantity limits are based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Evidence-based Uses and Clinical Efficacy	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓

Cost Effectiveness	✓	✓

Evidence-based Uses and Clinical Efficacy means: 1) Potentially unsafe and ineffective dose escalation - Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule; Drug or drug class has potential for being prescribed for periods of time exceeding the recommended duration of therapy or when therapy ceases to provide benefit; Drug or drug class has no evidence or data regarding efficacy at doses above the FDA approved limit; Drug or drug class has evidence that increasing the dose past the FDA approved limits does not provide improved efficacy. 2) Dose Optimization - Drug or drug class has evidence that the number of dosage units can be reduced by using a higher strength formulation of the drug without compromising efficacy. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time,

forgetting to take a dose, or stopping the medication too soon. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
    Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, including drugs that may be equally efficacious and less costly; 2) High utilization - Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits. An NQTL may be applied to ensure dosing follows the FDA approved limit and is in alignment with the FDA labeled indication(s). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations

  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including quantity limits, and the development of coverage criteria for drugs that require quantity limits, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require quantity limits for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in quantity limits programs and upon which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1)

Evidence-based uses and clinical efficacy; (2) Risk of abuse, misuse, addiction or diversion; (3) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including quantity limits, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs.

The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy
Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a Caremark Medical Director, and by external clinical experts whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology

MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to M/S drugs in the prescription drug benefit classifications. Caremark policies related to quantity limits include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) non-quantitative treatment limitations (NQTLs), to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.

FormDevMgmt.pdf	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process, including as applicable for prior authorization requests for exceptions to quantity limits, for plans subject to Virginia (VA) state laws.

INCLUDING A DRUG OR DRUG CLASS IN QUANTITY LIMITS PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in quantity limits programs and upon which development of coverage criteria are based are: (1) Evidence-based uses and clinical efficacy; (2) Risk of abuse, misuse, addiction or diversion; (3) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in quantity limits programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (prior authorization, step therapy or quantity limits) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary source, must support the coverage conditions of the quantity limits requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard CVS Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within CVS Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply quantity limits to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.
- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The type(s) of NQTL (prior authorization, quantity limit or step therapy) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.
- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.

- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs (including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION- UTILIZATION MANAGEMENT DESIGN PROCESS
DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets

parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.
   v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.
   vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustrative purposes only and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil)

	MH/SUD: Yes **M/S:** No **Therapeutic Category:** Stimulants (Miscellaneous)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • Narcolepsy
	  • Shift Work Disorder (SWD)

Step 3.	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective. Accessed 06-09-25 • Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil). Accessed 06-10-25 ▪ Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy. • Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893. Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil).
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance.
  Accessed 06-09-25

Off-label Prescribing Patterns. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications.
  Accessed 06-09-25

	• Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. ◦ CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.

Step 5	The sources that were used and documented for armodafinil include:
	• Prescribing information for armodafinil (Nuvigil)
	• Drug information Databases and compendia
	  ◦ Lexicomp AHFS DI
	  ◦ Micromedex
	• Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.
	• Summary of Coverage Conditions:
	  ◦ Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  ◦ Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  ◦ Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification

	• Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy. • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil. • Reason for Type of NQTL • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy. • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil): ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days
	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION (INCLUDING QUANTITY LIMITS EXCEPTION REQUESTS)

Caremark performs utilization management on Aetna's behalf. Its policies are used to determine operational aspects of prior authorization. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting prior authorization for both M/S and MH/SUD drugs. This policy documents the requirements for the prior authorization process for plans subject to Virginia (VA) laws. Physicians, patients, or a person appointed to manage the patient's care designated as an authorized representative can request prior authorization or exceptions to quantity limits, and prior authorization requests for exceptions to quantity limits are handled pursuant to this policy which applies equally to MH/SUD and M/S drugs. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.

i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.

i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:

a. Urgent PA Reviews will be completed within 24 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48

hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.

2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.

a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

c. Notification will be provided within 24 hours of making the adverse determination.

3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:

a. Urgent step therapy requests will be completed within 24 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;
ii. The reason(s) for the Adverse Determination;
iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;
iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;
v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;
vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.
vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs are subject to quantity limits, the development of coverage criteria, and the process of conducting prior authorization of requests for exceptions to quantity limits, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to quantity limits for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply quantity limits with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply quantity limits with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to M/S drugs.

As discussed in Step 4 above, the application of quantity limits within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for quantity limits exception requests are identical across both benefit categories. The operation of the quantity limits process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation comparative analysis is conducted by reviewing the following:

- Prior Authorization/Quantity limits Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – QUANTITY LIMITS EXCEPTIONS

Evaluation of denial rates for M/S and MH/SUD quantity limits exceptions requests is one measure that can evaluate whether quantity limits are applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects quantity limits decisions for MH/SUD and M/S drugs on the **Aetna Exchange Formulary for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied available through the date of this submission.

Approval/Denial Rates – Quantity Limits Exceptions			
VIRGINIA - Aetna Exchange Formulary – 2025			
Drug Type	**MED/SURG**	**MH**	**SUD**
Total Requests	803	195	11
Total Approvals	703	177	10
Total Denials	100	18	1
Approval Percent	87.5%	90.8%	90.9%
Denial Percent	12.5%	9.2%	9.1%
Average TAT in Days	0.043	0.073	0.009

This data reflects that overall, **90.8%** of quantity limits exceptions for MH drugs were approved, and **87.5%** of M/S drugs were approved. **90.9%** quantity limits exception requests for SUD drugs were approved. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs were less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying utilization management to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its delegate, Caremark, audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or Med Surg condition.
- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria

questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In summary, based upon review of the data and information addressed herein, Aetna may conclude that the processes, strategies, evidentiary standards or other factors used in designing and applying utilization management, including quantity limits, with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying quantity limits with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its Pharmacy Benefit Manager, Caremark, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Quantity limits refers to a limitation that establishes a maximum quantity of a drug that is covered over a specified period

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to utilization management including quantity limits, and the development of coverage

criteria for drugs that require quantity limits, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of quantity limits. As noted in **Step 3**, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to quantity limits and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to quantity limits in a comparable manner, and the MH/SUD drugs to which quantity limits applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that quantity limits are designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4,** as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to quantity limits, the development of coverage criteria for drugs that require quantity limits, and the process of conducting prior authorization for quantity limits exception requests. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply quantity limits. That analysis shows that no separate policies or procedures exist with respect to quantity limits for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying quantity limits in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, quantity limits are designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and are not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, quantity limits are applied in a comparable manner for both M/S and MH/SUD drugs. The application of quantity limits within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs.

Further, the operational procedures for quantity limits are identical across both benefit categories. The operation of the prior authorization process for quantity limits demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of quantity limits approval and denial rates, which demonstrated lower rates of denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating to utilization management coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases demonstrated that the process for reviews was consistent across all utilization management requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying quantity limits to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: STEP THERAPY
VIRGINIA: EXCHANGE FORMULARY – AETNA 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Step Therapy

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® (hereinafter sometimes "PBM" or "Caremark"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Step Therapy (hereinafter sometimes "ST") refers to criteria that define the circumstances under which a drug requiring prerequisite therapy will be systematically paid under a prescription benefit or reviewed through the prior authorization process. For MH/SUD and M/S drugs subject to a step therapy requirement, prior authorization is required. Prior authorization of prescription drugs subject to a step therapy requirement is conducted by the Caremark Prior Authorization Department using pre-established medical necessity guidelines developed by Caremark. In the prescription drug benefit classification, the following materials describe step therapy:

1. PLAN DOCUMENTS

Certificate of Coverage: HPOL 04 SERFF# AETN-133977008

Step therapy is a type of **precertification** where you must try one or more prerequisite drugs before a step therapy drug is covered. A 'prerequisite' is something that is required before something else. Prerequisite drugs are FDA-approved, may cost less and treat the same condition. If you don't try the prerequisite drugs first, the step therapy drug may not be covered.

Contact us or go online to get the most up to date **precertification** requirements and list of step therapy drugs.

2. DRUG GUIDE

The Drug Guide includes important information for members pertaining to step therapy, including identification of M/S and MH/SUD medications requiring step therapy. The most current version is publicly available at:

Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information pertaining to step therapy. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies describe step therapy:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management programs.

CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the utilization management process for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: EXCHANGE FORMULARY 2025 DRUG GUIDE 2025_Aetna_Health _Exchange_Plan.pdf	
Benefit classifications to which NQTL applies: ✔ Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) including a drug or drug class in step therapy programs; and b) development of coverage criteria. Caremark develops standard formularies and assigns utilization management designations such as prior authorization, step therapy, and quantity limits based on clinical, safety and cost-effectiveness factors supported by nationally recognized evidence and guidelines.

(a) Factors for including a drug or drug class in step therapy programs.

The determination of which drugs are subject to utilization management, including step therapy, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including step therapy, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in step therapy programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a

drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2)Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label

- FDA Online Label Repository
- FDA Drug Safety-related Labeling Changes (SrLC)
- FDA Drug Trial Snapshot
- Disease specific Clinical Practice Guideline Protocols
- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong

time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**

- CMS.gov
- Individual state regulations sites
- Health and Human Services (HHS.gov)
- Healthcare.gov
- NCQA.org
- URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts

- Internal business partner consultation

(b) Factors for the development of coverage criteria

The development of coverage criteria for drugs that require step therapy is based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology

- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2)Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR),

Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information

- Clinical evidence determined to be experimental, investigational or unproven
- Clinical Practice Guidelines
- Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)

- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs

- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
- CVS Caremark® Drug Trend Report
- Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)
  - Healthcare.gov
  - NCQA.org
  - URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population

and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including step therapy, and the development of coverage criteria for drugs that require step therapy, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require step therapy for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in step therapy programs and upon

which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including step therapy, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs. The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark® template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy

Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a CVS Caremark Medical Director, and by external clinical experts. whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the clinical criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology

MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to M/S drugs in the prescription drug benefit classifications. Caremark policies related to step therapy include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs UM NQTLs (prior authorization, step therapy, quantity limits), to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management programs.

CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the utilization management process for plans subject to Virginia (VA) state laws.

INCLUDING A DRUG OR DRUG CLASS IN STEP THERAPY PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in step therapy programs and upon which development of coverage criteria is based are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in step therapy programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (step therapy, quantity limits, prior authorization) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary

source, must support the coverage conditions of the step therapy requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark® policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply step therapy to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.
- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The

type(s) of NQTL (prior authorization, step therapy, quantity limits) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.

- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.
- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs

(including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION-
UTILIZATION MANAGEMENT DESIGN PROCESS DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's (PA, ST, QL) development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.
   v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.

vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustration only, and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil) **MH/SUD:** Yes **M/S:** No **Therapeutic Category:** Stimulants (Misc.)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • NarcolepsyShift Work Disorder (SWD)

Step 3.	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use. Sources reviewed for this factor:

	• Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective. Accessed 06-09-25 • Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil). Accessed 06-10-25 ▪ Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy. • Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893. Accessed 06-10-25 **Patient Population/Monitoring Considerations/Treatment Complexity** – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information. Accessed 06-09-25 • Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring. • 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504. Accessed 06-10-25 • 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276. Accessed 06-10-25 • 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023. Accessed 06-10-25 • 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394. Accessed 06-10-25 • 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945. Accessed 06-10-25 **Risk of Abuse, Misuse, Addiction or Diversion**- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing.

	Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil). Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 **Off-label Prescribing Patterns**. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. • CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.

Step 5	The sources that were used and documented for armodafinil include:
	• Prescribing information for armodafinil (Nuvigil)
	• Drug information Databases and compendia
	  • Lexicomp AHFS DI
	  • Micromedex
	• Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.

	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification
	  • Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy.
	  • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil.
	• Reason for Type of NQTL
	  • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy.
	  • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil):
	  ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days
	  ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days

	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION (INCLUDING FOR MH/SUD AND M/S DRUGS THAT REQUIRE STEP THERAPY)

Caremark performs utilization management on behalf of Aetna. Its policies are used to determine operational aspects of prior authorization conducted for drugs that require step therapy. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting reviews for M/S and MH/SUD drugs, including drugs that have a step therapy requirement. This policy documents the requirements for

the prior authorization process, including for step therapy, for plans subject to Virginia (IN) laws. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.
    i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.
    i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

    ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

    i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

    ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

    iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

    iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:
    a. Urgent PA Reviews will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.
2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.
    a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
    b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    c. Notification will be provided within 24 hours of making the adverse determination.
3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:
    a. Urgent step therapy requests will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the

missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;

ii. The reason(s) for the Adverse Determination;

iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;

iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;

v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;

vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.

vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs require step therapy, the development of coverage criteria, and the process of conducting prior authorization of MH/SUD and M/S drugs subject to a step therapy requirement, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to step therapy for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply step therapy with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other

factors used to design and apply step therapy with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to M/S drugs.

As discussed in Step 4 above, the application of step therapy within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for prior authorization of M/S and MH/SUD drugs that require step therapy are identical across both benefit categories. The operation of the step therapy process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation analysis is conducted by reviewing the following:

- Prior Authorization/Step Therapy Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – STEP THERAPY

Evaluation of denial rates for M/S and MH/SUD step therapy requests is one measure that can evaluate whether step therapy is applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects step therapy decisions for MH/SUD and M/S drugs on the **Aetna Exchange Formulary – Aetna for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied.

Approval/Denial Rates – Step Therapy Exceptions			
VIRGINIA - Aetna Exchange Formulary – 2025			
Drug Type	MED/SURG	MH	SUD
Total Requests	1,009	303	-
Total Approvals	835	260	-
Total Denials	174	43	-
Approval Percent	82.8%	85.8%	0.0%
Denial Percent	17.2%	14.2%	0.0%
Average TAT in Days	0.153	0.156	-

This data reflects that overall, **85.8%** of **step therapy** requests for MH drugs were approved, and **88.8%** of M/S drugs were approved. There were no step therapy requests for SUD drugs. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs was less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying utilization management to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its delegate Caremark audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies. Since there were no requests specific to the Exchange, cases from the Aetna Advanced Control and Exchange formularies were utilized for the audit to evaluate the application of the NQTL, overall.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA

requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or Med Surg condition.

- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In sum, based upon review of the data and information addressed herein, Aetna concludes that the processes, strategies, evidentiary standards or other factors used in designing and applying step therapy with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying step therapy with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its PBM, Caremark, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Step therapy refers to criteria that define the circumstances under which a drug requiring prerequisite therapy will be systematically paid under a prescription benefit or reviewed through the prior authorization process.

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to step therapy requirements, and the development of coverage criteria for drugs that require step therapy, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of step therapy. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to step therapy and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to step therapy in a comparable manner, and the MH/SUD drugs to which step therapy applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that step therapy is designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to step therapy, the development of coverage criteria for drugs that require step therapy, and the process of conducting prior authorization for M/S and MH/SUD drugs subject to step therapy. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply step therapy. That analysis shows that no separate policies or procedures exist with respect to step therapy for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying step therapy in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, step therapy is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, step therapy is applied in a comparable manner for both M/S and MH/SUD drugs. The application of step therapy within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs. Further, the operational procedures for conducting prior authorization for drugs subject to step therapy are identical across both benefit categories. The operation of the prior authorization process for step therapy demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of step therapy approval and denial rates, which demonstrated lower rates of step therapy denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer utilization management coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases demonstrated that the process for reviews was consistent across all utilization management requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying step therapy to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
FORMULARY DESIGN/TIERING
VIRGINIA: STANDARD OPT OUT FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Formulary Design/Tiering

A formulary is the list of generic and brand medications covered by a health benefit plan. The formulary contains tiers based on a drug's preferred or non-preferred status, and specialty or non-specialty status.

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefits Manager, CVS Caremark® (sometimes referred to as "PBM" or "Caremark"), including formulary management. The PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the Five (5) Tier Standard Opt Out Formulary – Aetna ("SOO-Aetna") formulary. The PBM's tiered formulary structure designates drugs as generic or brand, designates brand drugs as preferred or non-preferred, and designates drugs as specialty or non-specialty. Aetna further designates generic drugs as preferred and non-preferred and assigns cost share ranges to each tier. The Certificate of Coverage and Schedule of Benefits filed and approved by the state of Virginia support a variable range of member cost shares. There is no separate cost-share structure for MH/SUD drugs and M/S drugs. In accordance with 29 C.F.R. § 146.136(c)(3)(iii)(A), applicable to multi-tiered prescription benefits, the different levels of financial requirements are applied to different tiers of prescription benefits based on reasonable factors determined in accordance with rules relating to requirements for NQTLs and without regard to whether a drug is generally prescribed with respect to M/S benefits or MH/SUD benefits. The tiered benefit and cost-share design encourages generic utilization and lower pharmacy cost through copay differentials and encourages behaviors that will ultimately lead to appropriate utilization of cost-effective generics and preferred brand drugs.

In the prescription drug benefit classification, the following materials describe formulary design/tiering:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Covered services are based on the drugs in the **drug guide**. We exclude **prescription** drugs listed on the formulary exclusions list unless we approve a medical exception. The formulary exclusions

list is a list of **prescription** drugs not covered under the plan. This list is subject to change. If it is **medically necessary** for you to use a **prescription** drug that is not on this **drug guide**, you or your **provider** must request a medical exception. See the *Requesting a medical exception* section or just contact us.

The pharmacy may substitute a **generic prescription drug** for a **brand-name prescription drug**. Your cost share may be less if you use a **generic drug** when it is available.

Where your schedule of benefits fits in

The schedule of benefits shows any out-of-pocket costs you are responsible for when you receive **covered services** and any benefit limitations that apply to your plan. It also shows any **maximum out-of-pocket limits** that apply.

Schedule of Benefits: HSOB 11 SERFF Tracking #AETN-134117030

The Schedule of Benefits provides the member cost shares for covered services as outlined in the Certificate of Coverage.

2. DRUG GUIDE

The drug guide indicates the tier of covered drugs. It also provides definitions and other information for members. The most current version is publicly available at: Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers. The most current version is publicly available at: Aetna Provider Manual

4. POLICIES AND PROCEDURES

The following materials describe formulary design/tiering:

Document #	Title	Description
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
CPANDT-0002	CVS Caremark® National Pharmacy and Therapeutics (P&T) Committee	This policy defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T)

		Committee as well as requirements regarding conflicts of interest, meeting administration, and formulary decisions.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the file attached below contains all MH/SUD and M/S prescription drugs covered under the prescription drug benefit. These drugs are therefore subject to formulary design/tiering.

VIRGINIA: AETNA – STANDARD OPT OUT FORMULARY 2025 SOO Formulary Tiering 2025.xlsx	
Benefit classifications to which NQTL applies: a Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs labeled as Medical/Surgical in the attached Drug File	▪ Prescription Drugs labeled as MH or SUD in the attached Drug File

Step 2:Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

Tier 1 Drug Placement

A drug's placement in **Tier 1** indicates that it is a generic medication. Generic drugs are medications that have the same active ingredients, strength, and effectiveness as brand-name drugs, but they usually cost less. They are approved by the FDA and work the same way in the body, but they do not carry the brand name. This Tier 1 generic strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Generic Status	✓	✓

Generic Status means, drugs/medications that have the same active ingredients, strength, and effectiveness as brand-name drugs, but they usually cost less. They are approved by the FDA and work the same way in the body, but they do not carry the brand name. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Generic Status
- **Sources:**
  - Medi-Span Drug Database Brand Generic Reference

Additionally, generic drugs are placed on Tier 1 (as preferred generic) or Tier 3 (non-preferred generic). Indication of preferred and non-preferred generic status means the generic drug costs less (preferred) or more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 2 Drug Placement

A drug's placement in **Tier 2** indicates that it is considered a preferred brand-name medication. This designation is based on Caremark's preferred tier strategy, which evaluates brand/generic availability, and cost-effectiveness. The strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Financial Net Cost	✓	✓

Financial Net Cost means: The estimated total cost of a drug to the plan, calculated after accounting for wholesale acquisition cost (WAC), negotiated rebates, price concessions, or other financial incentives. Net cost is used as a financial factor as part of the assessment of a brand-name drug for inclusion as a preferred brand (Tier 2) on the formulary. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Pricing analyzed using a standard cost-model based on the drug's WAC minus rebates or another uniform pricing formula, applied consistently across all drugs within a therapeutic class.
- **Sources**
  - Medi-Span Drug Database Brand Generic Reference and WAC
  - Manufacturer Agreements (Applicable rebates)
  - Rx Claim PBM Database (WAC and script utilization by formulary)
  - FDA labeling

Tier 3 Drug Placement

A drug's placement in **Tier 3** indicates that it is a non-preferred brand. This Tier 3 strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Factor	Applicable to M/S	Applicable to MH/SUD
Financial Net Cost	✓	✓

Financial Net Cost means: The estimated total cost of a drug to the plan, calculated after accounting for wholesale acquisition cost (WAC), negotiated rebates, price concessions, or other financial incentives. Net cost is used as a financial factor as part of the assessment of a brand-name drug for inclusion as a preferred brand (Tier 2) on the formulary. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Pricing analyzed using a standard cost-model based on the drug's WAC minus rebates or another uniform pricing formula, applied consistently across all drugs within a therapeutic class.
- **Sources**
  - Medi-Span Drug Database Brand Generic Reference and WAC
  - Manufacturer Agreements (Applicable rebates)
  - Rx Claim PBM Database (WAC and script utilization by formulary)
  - FDA labeling

Additionally, certain generic drugs are placed on Tier 3 (as non-preferred generic). which means the generic drug costs more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined to be non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 4 and Tier 5 Drug Placement

Factor	Applicable to M/S	Applicable to MH/SUD
Specialty Drug Status	✓	✓

Specialty drug designation is based on review and recommendation by a cross-functional clinical committee that evaluates clinical complexity, cost, and other relevant criteria. MH/SUD and M/S drugs designated as specialty medications are placed on Tiers 4 and 5, based upon whether the drug is identified as a preferred or non-preferred drug, as defined above. Drugs that are designated as specialty preferred are placed in Tier 4, and drugs designated as specialty non-preferred are placed in Tier 5. This strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

As set forth in Step 2, the factors used to determine a drug's tier placement are 1) generic status; 2) net cost; 3) specialty drug status. This section explains how these factors are used to determine drug tier placement. Based upon these factors, Aetna's PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the 5 tier SOO-Aetna formulary. The PBM's tiered formulary structure designates drugs as generic or brand, designates brand drugs as preferred or non-preferred, and designates drugs as specialty or non-specialty. Aetna further designates generic drugs as preferred and non-preferred, and assigns cost share ranges to each tier. The determination of which drugs are placed into each tier is based upon the same factors, strategies, and processes, and is evaluated consistently, regardless of therapeutic category, and without regard to whether the drug is used to treat M/S or MH/SUD conditions.

In making formulary decisions, Caremark considers clinical, financial, and market factors. All formulary decisions are approved by the CVS Caremark National Pharmacy & Therapeutics (P&T) Committee, which is an independent, external body. The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the formulary tiering process:

- The Formulary Administration team is comprised of analysts and pharmacists and oversees the standard template formulary development and management. The team monitors new drug databases, reviews the sources and evidentiary standards, conducts the drug evaluations, and provides information about placement on the formulary and tier assignment.
- The Formulary Review Committee (FRC) is comprised of individuals with expertise in pharmacy benefit management. This committee makes final recommendations for drug inclusions and tier placements for the CVS Caremark National Pharmacy and Therapeutics Committee's (P&T Committee) review and approval for template formularies. The FRC meets a minimum of 10 times per year and on an ad hoc basis as needed, to discuss and review proposals for formulary changes.
- The Clinical Formulary team is comprised of analysts and pharmacists and develops drug information documents. These documents are shared with other teams and experts involved in formulary development and the P&T Committee.
- The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds

and/or academic expertise regarding prescription drugs, and it meets at least quarterly. The committee's role with respect to tiering determinations is advisory in nature.

The FRC and P&T Committee members include experts from a variety of clinical fields including behavioral health, as well as experts in pharmacy benefits management.

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CVS Caremark Personnel Titles, Credentials and Committees Composition

The **Formulary Administration Department** oversees the standard template formulary development and management.

Job Title, Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Lead Director, Pharmacist
Sr Managers, Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Formulary Department** writes drug information materials in support of the P&T Committee.

Job Title, Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Lead Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analysts

The **Formulary Review Committee (FRC)** makes business recommendations. It includes individuals with expertise in pharmacy benefit management.

Voting Members Job Title, Credential	Business Unit
Lead Director Chairperson	Trade Relations
VP, Pharmacist	Product Development - Sales
Executive Director, MBA	Finance
Executive Director, MBA	Trade Relations
AVP, Pharmacist	Medical Affairs
Sr Manager, Pharmacist	Clinical Client Operations

The **P&T Committee**, an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs.

Voting Members, Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Internal Medicine
MD – Cardiology	MD – Infectious Disease

MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
PharmD – Gerontology	MD – Adult Psychiatry
MD – Gerontology	MD – Pediatric Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Advocate

Tier 1 Drug Placement

1. The generic status factor is used to determine tier placement as follows: A licensed PBM pharmacist reviews the drug specific source to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for Tier 1 placement. The drug database with Medi-Span information is queried by a licensed PBM pharmacist to locate the drug-specific Brand Generic Reference information section.

2. If the Brand Generic Reference is equal to "Y-GENERIC"; then the drug is generic is placed on Tier 1.

The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

The following scenario is assessed to identify if the standard is met. If **the scenario** applies to the drug, then the drug is considered a generic drug: a licensed PBM pharmacist reviews the Brand Generic Reference information to determine whether a drug qualifies as generic for Tier 1 placement. This scenario is consistently evaluated across all drug classes without regard to whether the drug is used to treat MH/SUD or M/S conditions.

Additionally, generic drugs are placed on Tier 1 (as preferred generic) or Tier 3 (non-preferred generic). Indication of preferred and non-preferred generic status means the generic drug costs less (preferred) or more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy are applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Tier 2 Drug Placement

The Financial Net Cost factor is used to determine tier placement as follows: Individuals with expertise in pharmacy benefit management review the drug and disease-specific sources to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for Tier 2 preferred brand status. Therapeutic classes include brand and/or generic drugs that treat

similar conditions and compete with each other in the market. Net costs are calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.

The therapeutic categories are reviewed annually to evaluate any future changes based on new market entrants, changes in pricing or rebate contracts. Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable clinical and economic balance. Market factors such as supply chain durability (e.g., drug shortages) are also considered when no brands are preferred or only generics are covered. The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

Therapeutic Class Evaluation: Drugs are grouped and reviewed by therapeutic class. The therapeutic class framework allows for the identification of the product that offers the best overall value considering both clinical effectiveness, market conditions and net cost.

Net Cost Modeling: Net cost is calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.

Any of the following modeling scenarios could result in preferred brand designation:

1. Lowest net cost among brands (rebate-adjusted)
    - The brand offers the lowest WAC minus rebate among all brands in the class.
    - Generic alternatives may or may not exist within a therapeutic class.

2. Broader Indications
    - The brand has unique or broader indications relative to other brands in the drug category.
    - Net cost is competitive—even if not the lowest relative to other brands

3. Limited generic availability
    - A generic version exists but it may have supply constraints in the market which may require coverage of the brand
    - The brand is temporarily maintained as covered on formulary which may be in the preferred tier or non-preferred brand tier while the shortage of the generic version persists.

These scenarios are consistently evaluated across all drug classes without regard to whether the drug is used to treat MH/SUD or M/S conditions.

Tier 3 Drug Placement

The Financial Net Cost factor is used to determine tier placement as follows: Individuals with expertise in pharmacy benefit management review the drug and disease-specific sources to identify characteristics that meet the evidentiary standard whenever a new or existing drug is evaluated for

Tier 2 preferred brand status, as mentioned above. Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable balance of clinical and economic value, as well as market factors such as supply chain durability (e.g., drug shortages) across the therapeutic class, either because no brands are preferred or only generics are covered. Non-preferred brand content is derived from the remaining products that are not placed on Tier 1 or 2. The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated.

Methodology Detail:

The following scenario is assessed to identify if the standard is met. If the scenario applies to the brand drug, then the drug is assigned to Tier 3.

Net Cost Evaluation

- Products Net cost is calculated by using the drug's WAC derived from Medi-Span drug database minus any applicable rebates derived from manufacturer contracts.
- Preferred brand (Tier 2) placement is supported by modeling scenarios in which one or more brand drug(s) demonstrate the most favorable balance of clinical and economic value
- Tier 3 non-preferred brand content is derived from remaining products that are not placed on Tier 1 or 2, which do not demonstrate the most favorable economic value.

This scenario is consistently evaluated across all drug classes without regard to whether the drug used to treat MH/SUD or M/S conditions.

Additionally, certain generic drugs are placed on Tier 3 (non-preferred generic). Indication of non-preferred generic status means the generic drug costs less more (non-preferred) than other generic drugs used for the same purpose and treat the same condition. Generic drugs are determined as preferred or non-preferred based on evaluation of cost compared to other generic medications available in that drug class. This evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

<u>Tier 4 and 5 Drug Placement</u>

Drug placement on Tiers 4 and 5 indicate that the drug is designated as a specialty drug. Specialty drug designation is based on review and recommendation by a cross-functional clinical committee that evaluates clinical complexity, cost, and other relevant criteria. Caremark adopts specialty drug status in connection with its standard formulary development process, and this designation is reflected in Aetna's formularies. MH/SUD and M/S drugs designated as specialty medications are placed on Tiers 4 and 5, based upon whether the drug is identified as a preferred or non-preferred drug, as defined above. Drugs that are designated as specialty and preferred are placed in Tier 4, and drugs designated as specialty and non-preferred are placed in Tier 5.

The same methodology is applied across all drug classes. No differences exist in how MH/SUD and M/S drugs are evaluated, designated as specialty drug, and placed on Tiers 4 and 5. This

evaluation and strategy is applied uniformly across all therapeutic categories, including treatments for MH/SUD and M/S conditions.

Relationship, ordering and weighting of multiple factors:

The factors listed above are interrelated, but apply to distinct formulary tiers, including Tiers 1-5 of the standard SOO-Aetna formulary. No factor is weighted more heavily than the other, and all operate together to ensure employment of a formulary design that encourages appropriate utilization of cost-effective drugs. The determination of which drugs are placed into each tier is based upon the same factors, strategies, and processes, and is evaluated consistently, regardless of therapeutic category, and without regard to whether the drug is used to treat M/S or MH/SUD conditions.

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering with respect to M/S drugs in the prescription drug benefit classification. CVS Caremark materials related to formulary design/tiering include:

Document #	Title	Description
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
CPANDT-0002	CVS Caremark National Pharmacy and Therapeutics (P&T) Committee	This policy defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee as well as requirements regarding Conflict of Interest, meeting administration, and formulary decisions.

The determination of which drugs are placed into each tier is based upon the same strategies and processes regardless of therapeutic category. Factors and evidentiary standards are applied

consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions.

As written, the **Formulary Development and Management at CVS Caremark** document describes the underlying principles of the CVS Caremark formulary management and development process, and provides information about the groups involved in decision-making and oversight. There is no distinction between processes and committees used for M/S and MH/SUD drugs. The process for the development and management of the formulary, including committee members and meetings, is the same regardless of drug category.

As written, **Policy CPANDT-0002 CVS Caremark National Pharmacy and Therapeutics (P&T) Committee** defines the composition, role, and responsibilities of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee, including membership, meeting administration and formulary decisions. All members of the P&T Committee are independent contractors that are clinical experts from a variety of medical specialties that include both M/S and MH/SUD practitioners. Pursuant to this policy, the CVS Caremark National P&T Committee will review and approve drugs for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the formulary. Further, the CVS Caremark National P&T Committee will ensure that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states from a formulary and utilization management perspective. This policy applies generally to both M/S and MH/SUD drugs.

Additionally, the following provides a demonstration of how factors are applies to MH/SUD and M/S drugs for various tiers. The specific drugs in the following section were selected for illustrative purposes.

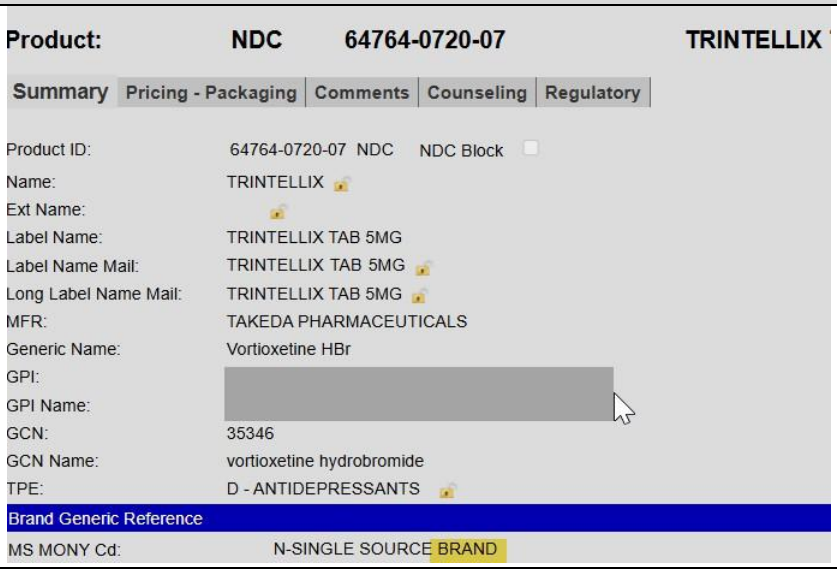
Tier 1 Drug Placement

The demonstration below illustrates how the factors are applied to MH/SUD and M/S drugs.

Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Captopril **MH/SUD:** No **Drug Group Description:** Antihypertensives		**Tier 1** Source confirms GENERIC This generic drug is placed in Tier 1.

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Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Duloxetine **MH/SUD:** Yes - MH **Drug Group Description:** Antidepressants		**Tier 1** Source confirms GENERIC This generic drug is placed in Tier 1.
Drug Name: Vivjoa **MH/SUD:** No **Drug Group Description:** Antifungals		Source confirms BRAND This brand drug is NOT placed in Tier 1.

Drug Information	Source and Supporting Information	Tier Placement
Drug Name: Trintellix **MH/SUD:** Yes **Drug Group Description:** Antidepressants		Source confirms BRAND This brand drug is NOT placed in Tier 1.

Tier 2 Drug Placement

The following section illustrates how the preferred brand designation methodology is applied in practice using two representative drugs—one used to treat a MH/SUD condition, and one used to treat a M/S condition. These examples demonstrate the consistent application of the preferred brand designation criteria across therapeutic classes.

Note: While the methodology to determine brand coverage is applied consistently across all drug categories, the specific modeling scenarios may vary based on clinical and/or market dynamics—such as generic availability, market competition, or clinical indications. For example, many MH/SUD drug classes have high generic market penetration—often exceeding 90%—which significantly reduces the likelihood that a brand-name MH/SUD drug in that class will be selected for preferred status. In contrast, some MED/SURG drugs may not face the same degree of generic competition or may offer unique clinical attributes that justify a preferred designation despite higher cost. Accordingly, the differences in modeling scenarios reflect underlying market conditions and therapeutic class characteristics, not inconsistency in how the tiering methodology is applied.

The demonstration below illustrates how the factors are applied in practice to MH/SUD and M/S drugs.

Drug Name Qelbree
MH/SUD Yes
Category Attention Deficit Hyperactivity Disorder Non-Stimulants

Applicable Modeling Scenario # 1

ADHD Non-Stimulants	
BRAND	**Generic**
not available	clonidine ER
Intuniv	guanfacine ER
Onyda XR	*not available*
Qelbree	*not available*
Strattera	atomoxetine

- **Generic Alternatives**: atomoxetine, clonidine ER, guanfacine ER
- **Generic market share**: > 90% as measured by claims volume
- **Other brands**: Intuniv, Onyda XR, Strattera
- **WAC** derived from Medi-Span drug database:
  - Qelbree $520 (30-day supply)
  - Intuniv $370 (30-day supply) (Generic Available)
  - Onyda XR $480 (30-day supply)
  - Strattera $505 (30-day supply) (Generic Available)
- Any applicable rebates derived from manufacturer contracts
- Qelbree net costs are less by 9% to 16% compared to other branded products when the rebates are applied
- Generic costs are $52 for a 30-day supply and are less than preferred branded products (net of rebates) by a factor of 8 times

Tier Designation: Based on clinical factors, net costs of all products in the category, and market dynamics, Qelbree tier placement is preferred at the lowest branded tier, with all other brands at a higher tier or not covered. Generics are still the most preferred (Tier 1) agents.

Drug Name Austedo
MH/SUD No
Category Movement Disorders Huntington's Disease/Tardive Dyskinesia

Applicable Modeling Scenario: 2

Movement Disorders	
BRAND	**Generic**
Austedo	*not available*
Ingrezza	*not available*
Xenazine	tetrabenazine

- **Generic Alternatives**: tetrabenazine
- **Generic market share**: approximately 10% as measured by claims volume
- **Other brands**: Ingrezza, Xenazine
- **WAC** derived from Medi-Span drug database:
  - Austedo $7,960 (30-day supply)
  - Ingrezza $7,999 (30-day supply)
  - Xenazine $22,788 (30-day supply) (Generic Available)
- Applicable rebates derived from manufacturer contracts
- Based on WAC less rebates to derive lowest net cost, Ingrezza is the least expensive brand, with the net cost of Austedo 7% to 12% higher. Branded Xenazine has a net cost approximately 3.5 times higher (350%) than either of the other brand products.

- Generic costs for a 30-day supply of tetrabenazine are $4,715 and are less than branded products (net of rebates) by 27% to 30%
- Note, generic Tetrabenazine, which treats Huntington's Disease only, requires use multiple times daily vs. branded Austedo which treats both Huntington's Disease and Tardive Dyskinesia. Ingrezza only treats Tardive Dyskinesia.

Tier Designation: Austedo and Ingrezza are preferred at the lowest branded tier. Ingrezza is the lowest-net product in the class but only treats Tardive Dyskinesia; Austedo treats both Huntington's Disease and Tardive Dyskinesia. Factoring in the clinical profiles with the economic factors, both Ingrezza and Austedo are placed in a preferred brand tier, with Xenazine, which has a generic alternative, not covered.

Tier 3 Drug Placement

The demonstration below illustrates how the factors are applied in practice.

Drug Name Rexulti
MH/SUD Yes
Category Antipsychotics – Atypical

Applicable Modeling Scenario # 1

- **Generic Alternatives**: aripiprazole, asenapine, clozapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone
- **Generic market share**: 86% as measured by claims volume
- **Other brands**: Caplyta, Rexulti, Vraylar
- **WAC** derived from Medi-Span drug database:
  - Caplyta $1,672 (30-day supply)
  - Rexulti $1,485 (30-day supply)
  - Vraylar $1,444 (30-day supply)
- Any applicable rebates derived from manufacturer contracts
- All branded products with generic alternatives excluded
- Vraylar net costs are less by 10% to 21% compared to other branded products when the rebates are applied
- Rexulti net costs are less by 12% compared to other branded products when the rebates are applied
- Generic costs are $17 for a 30-day supply and are less than branded products (net of rebates) by a factor of 60 times

Antipsychotics - Atypical	
BRAND	**Generic**
Caplyta	*not available*
Rexulti	*not available*
Vraylar	*not available*
Abilify	aripiprazole
Versacloz	clozapine
Latuda	lurasidone
Zyprexa	olanzapine
Invega	paliperidone
Seroquel	quetiapine
Fanapt	*not available*
Risperdal	risperidone
Clozaril	clozapine
Secuado	*not available*
Saphris	asenapine
Opipza	*not available*
Geodon	ziprasidone

Tier Designation: Based on clinical factors, net costs of all products in the category, and market dynamics, Rexulti placement is Tier 3.

Summary

The written materials discussed herein, pertaining to formulary design/tiering for MH/SUD and M/S drugs, all apply equally to MH/SUD and M/S drugs, and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2. No separate policies, procedures or documents exist with respect to formulary design and tiering for MH/SUD drugs as compared to

M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply formulary design/tiering with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply formulary design/tiering with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying formulary design/tiering with respect to M/S drugs. A review was conducted to evaluate the formulary status and tier assignment of MH/SUD and M/S drugs.

Testing Methodology

The input drug coverage extract file was processed and analyzed as follows:

- Using the Medi-Span Generic Product Identifier (GPI) therapeutic classification system, drugs with the same GPI code, brand/generic code, dosage form & strength, name, and route of administration were counted as one.
- Drugs were grouped into MH, SUD and M/S drug types, organized into formulary tiers, counted, and the totals were used to calculate the percentages of drugs in each tier by type.
- Drugs were grouped by preferred tiers, counted, and the totals were used to calculate the percentages with this preferred tier drug status.

To calculate the percent of drug type in each tier, the formula used is (X/Y)*100, where:

- X = the count of drugs of each type by tier
- Y = the total count of that drug type in the formulary

To calculate the percent of drug type with preferred formulary status, the formula used is [(A+B+C+…)/Y]*100, where:

- A, B, C, ... = the count of drugs of each type in preferred tiers
- Y = the total count of that drug type in the formulary

Results

The output formulary file attached in Step1, part 2 contains the drugs, formulary status, and tier assignment for the SOO-Aetna Formulary:

Formulary Tier Descriptions

- Tier 1 = Preferred Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands & Generics
- Tier 4 = Preferred Specialty
- Tier 5 = Non-Preferred Specialty

Formulary Tiering by Drug Type

Aetna - Standard Opt Out Formulary 2025

Drug Type	Results												
MED/SURG	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	0	2485	438	1313	733	306	0	0	0	0	0	5275	69.3%
	0.0%	47.1%	8.3%	24.9%	13.9%	5.8%	0.0%	0.0%	0.0%	0.0%	0.0%		
MH	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	0	634	48	169	25	8	0	0	0	0	0	884	80.0%
	0.0%	71.7%	5.4%	19.1%	2.8%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%		
SUD	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7	Tier 8	Tier 9	Tier 10	Total	Preferred
	0	95	7	10	2	1	0	0	0	0	0	115	90.4%
	0.0%	82.6%	6.1%	8.7%	1.7%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%		

In operation, the analysis and testing of the tiers shows that more MH/SUD drugs are placed within preferred tiers than M/S drugs, revealing that the factors and the sources are not used differently or more stringently with respect to MH/SUD compared to M/S drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs. Based upon review of the data and information addressed herein, Aetna may conclude that, in operation, the processes, strategies, evidentiary standards or other factors used in designing and applying formulary design/tiering with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying formulary design/tiering with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of its prescription drug benefit to its PBM, including formulary management. In the prescription drug benefit classification, a formulary is the list of generic and brand medications covered by a health benefit plan. The formulary contains tiers based on a drug's preferred or non-preferred status, and specialty or non-specialty status. The PBM establishes and provides Aetna with a tiered formulary structure that serves as the base of the 5 Tier SOO-Aetna formulary, and Aetna assigns cost share ranges to each tier. The Certificate of Coverage and Schedule of Benefits filed and approved by the state of Virginia support a variable range of member cost shares. There is no separate cost-share structure for MH/SUD drugs and M/S drugs.

Step 2 identified the factors that are used to design and apply formulary design/tiering to M/S and MH/SUD drugs, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of formulary design/tiering; there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, as written, to M/S and MH/SUD drugs, and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to formulary design/tiering in a comparable manner and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that formulary design/tiering is designed and applied in a comparable manner to MH/SUD and M/S drugs.

More specifically, as demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining formulary design/tiering for M/S and MH/SUD drugs. An as-written comparative analysis shows that no separate policies or procedures exist with respect to formulary design/tiering for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs, and the factors, sources and evidentiary standards are used in a comparable and no more stringent manner to determine formulary tier placement for MH/SUD and M/S drugs. This information and review demonstrate that, as written, formulary design/tiering is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

In addition, as demonstrated in **Step 5**, in operation, formulary design/tiering is applied in a comparable manner for both M/S and MH/SUD drugs. Testing of the formulary tiers and preferred drug composition shows that overall, a higher percentage of MH drugs and a higher percentage of SUD drugs are covered on preferred or lower cost tiers, compared to M/S. Accordingly, the factors, evidentiary standards and sources are not used differently or more stringently with respect to MH/SUD compared to M/S drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply formulary design/tiering to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying formulary design/tiering to M/S drugs. Moreover, in accordance with 29 C.F.R. § 146.136(c)(3)(iii)(A), applicable to multi-tiered prescription benefits, Aetna has demonstrated that different levels of financial requirements are applied to different tiers of prescription benefits based on reasonable factors determined in accordance with rules relating to requirements for NQTLs and without regard to whether a drug is generally prescribed with respect to M/S benefits or with respect to MH/SUD benefits.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Aetna Health Plan Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Health Plan Pharmacy (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: PRIOR AUTHORIZATION
VIRGINIA: STANDARD OPT OUT FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Prior Authorization

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® ("Caremark" or "PBM"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Prior authorization (hereinafter sometimes "PA") refers to a process that requires the prescribed use of a drug to be evaluated against a predetermined set of objective criteria before the prescription can be filled under a benefit plan. Prior authorization criteria documents define the circumstances under which a prior authorization medication should be paid under a prescription benefit plan. Prior authorization of prescription drugs is conducted by the Caremark Prior Authorization Department using pre-established medical necessity guidelines developed by Caremark.

In the prescription drug benefit classification, the following materials describe prior authorization:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Precertification
You need pre-approval from us for some **covered services**. Pre-approval is also called **precertification**.

Step therapy is a type of **precertification** where you must try one or more prerequisite drugs before a step therapy drug is covered. A 'prerequisite' is something that is required before something else. Prerequisite drugs are FDA-approved, may cost less and treat the same condition. If you don't try the prerequisite drugs first, the step therapy drug may not be covered.

Contact us or go online to get the most up to date **precertification** requirements and list of step therapy drugs.

Requesting a medical exception
Sometimes you or your **provider** may ask for a medical exception to get coverage for drugs that are not covered [or for **brand name** or **specialty drugs** or for which coverage was denied through **precertification** or **step therapy**. You, someone who represents you or your **provider** can contact us. You will need to provide us with clinical documentation. For directions on how you can submit a request for a review:
Call the toll-free number on your ID card
Go online at https://www.aetna.com
Submit the request in writing to:

CVS Health
ATTN: Aetna PA
1300 E Campbell Road
Richardson, TX 75081

2. DRUG GUIDE

The Drug Guide provides important information for members pertaining to prior authorization, including the medications requiring precertification. This list is subject to change. The most current version is publicly available at: Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information pertaining to prior authorization. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies describe prior authorization:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide attached below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: STANDARD OPT OUT FORMULARY 2025 DRUG GUIDE	
2025_Standard_Opt_Out_Aetna.pdf	
Benefit classifications to which NQTL applies: ✔ **Prescription Drug**	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**

▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

<u>Step 2</u>: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) including a drug or drug class in prior authorization programs; and b) development of coverage criteria. Aetna's PBM develops standard formularies and assigns utilization management designations such as prior authorization, step therapy and quantity limits based on clinical, safety and cost-effectiveness factors supported by nationally recognized evidence and guidelines.

(a) Factors for including a drug or drug class in prior authorization programs.

The determination of which drugs are subject to utilization management, including prior authorization, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including prior authorization, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in prior authorization programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓

Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2) Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information

  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia

  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards**:
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence

- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)
  - Healthcare.gov
  - NCQA.org
  - URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**

- FDA Orange Book
- FDA Purple Book
- FDA Drug-specific product label
- FDA Online Label Repository
- FDA Drug Trial Snapshot
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- CVS Caremark® Drug Claims Utilization
- Manufacturer Agreements or Rebate Contracts
- Internal business partner consultation

(b) Factors for the development of coverage criteria

The development of coverage criteria for drugs that require prior authorization is based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**

  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2) Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)

- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards**:
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)

- Healthcare.gov
- NCQA.org
- URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts

- Internal business partner consultation

<u>Step 3</u>: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including prior authorization, and the development of coverage criteria for drugs that require prior authorization, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require prior authorization for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in prior authorization programs and upon which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including prior authorization, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs. The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse

Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy
Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a Caremark Medical Director, and by external clinical experts whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the clinical criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology
MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to M/S drugs in the prescription drug benefit classifications. Caremark policies related to prior authorization include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization,

	Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark® Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure document the requirements for the prior authorization process for plans subject to Virginia (IN) state laws.

INCLUDING A DRUG OR DRUG CLASS IN PRIOR AUTHORIZATION PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in prior authorization programs and upon which development of coverage criteria is based are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in prior authorization programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (prior authorization, step therapy, quantity limits) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD

disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary source, must support the coverage conditions of the prior authorization requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard CVS Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply prior authorization to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.

- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The type(s) of NQTL (prior authorization, step therapy and/or quantity limits) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.
- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.
- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC

standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs (including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION- PRIOR AUTHORIZATION DESIGN PROCESS DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
    i. Factors considered: A list of factors used in the NQTL's (PA, ST, QL) development, with justification for each.
    ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
    iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
    iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
    v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
    i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
    ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
    iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
    iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to

the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.

v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.

vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustration only, and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil) **MH/SUD:** Yes **M/S:** No **Therapeutic Category:** Stimulants (Miscellaneous)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • Narcolepsy
	  • Shift Work Disorder (SWD)

Step 3	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established

in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective.
  Accessed 06-09-25
- Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil).
  Accessed 06-10-25

- Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy.
- Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
  Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

	Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil). Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 **Off-label Prescribing Patterns**. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. ◦ CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.
Step 5	The sources that were used and documented for armodafinil include: ◦ Prescribing information for armodafinil (Nuvigil) ◦ Drug information Databases and compendia ▪ Lexicomp AHFS DI ▪ Micromedex ◦ Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.
	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification
	  • Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy.
	  • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil.
	• Reason for Type of NQTL
	  • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy.
	  • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil):
	  ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days
	  ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days

	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION

Caremark performs utilization management on Aetna's behalf. Its policies are used to determine operational aspects of prior authorization. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting prior authorization for both M/S and MH/SUD drugs. This policy documents the requirements for the prior authorization process for plans subject to Virginia (VA) laws. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.

i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.

i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded

to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:
    a. Urgent PA Reviews will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.
2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.
    a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
    b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    c. Notification will be provided within 24 hours of making the adverse determination.
3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:
    a. Urgent step therapy requests will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;

ii. The reason(s) for the Adverse Determination;

iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;

iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;

v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;

vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.

vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs require prior authorization, the development of coverage criteria, and the process of conducting prior authorization, all apply equally to MH/SUD and M/S drugs and demonstrate

use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to prior authorization for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply prior authorization with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply prior authorization with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying prior authorization to M/S drugs.

As discussed in Step 4 above, the application of prior authorization within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for prior authorization—including submission requirements, review timelines, clinical documentation standards, and appeal processes—are identical across both benefit categories. The operation of the prior authorization process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation analysis is conducted by reviewing the following:

- Prior Authorization Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – PRIOR AUTHORIZATIONS

Evaluation of approval/denial rates for M/S and MH/SUD prior authorization requests is one measure that can evaluate whether prior authorization is applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects prior authorization decisions for MH/SUD and M/S drugs on the **Aetna Standard Opt Out Formulary for 2025**.

The data reflects the total number of decisions and the total number of decisions that were approved and denied.

Approval/Denial Rates – Prior Authorizations			
VIRGINIA - Aetna Standard Opt Out Formulary – 2025			
Drug Type	MED/SURG	MH	SUD
Total Requests	105	5	-
Total Approvals	78	4	-
Total Denials	27	1	-
Approval Percent	74.3%	80.0%	0.0%
Denial Percent	25.7%	20.0%	0.0%
Average TAT in Days	0.094	0.144	-

This data reflects that overall, **80.0%** of prior authorizations for MH drugs were approved, and **74.3%** of M/S drugs were approved. There were no prior authorization requests for SUD drugs. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs was less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying prior authorization to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its PBM, Caremark, audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA

requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or M/S condition.

- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In summary, based upon review of the data and information addressed herein, Aetna concludes that the processes, strategies, evidentiary standards or other factors used in designing and applying prior authorization with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying prior authorization with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its Pharmacy Benefit Manager, CVS Caremark®, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Prior authorization refers to a process that requires the prescribed use of a drug to be evaluated against a predetermined set of objective criteria before the prescription can be filled under a benefit plan. Prior authorization criteria documents define the circumstances under which a prior authorization medication should be paid under a prescription benefit plan.

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to prior authorization, and the development of coverage criteria for drugs that require prior authorization, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of prior authorization. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to prior authorization and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to prior authorization in a comparable manner, and the MH/SUD drugs to which prior authorization applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The

comparative analysis conducted above demonstrates that prior authorization is designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to prior authorization, the development of coverage criteria for drugs that require prior authorization, and the process of conducting prior authorization. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply prior authorization. That analysis shows that no separate policies or procedures exist with respect to prior authorization for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying prior authorization in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. CVS Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, prior authorization is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, prior authorization is applied in a comparable manner for both M/S and MH/SUD drugs. The application of prior authorization within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs. The operational procedures for prior authorization are identical across both benefit categories. The operation of the prior authorization process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of prior authorization approval and denial rates, which demonstrated lower rates of prior authorization denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating prior authorization coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases

demonstrated that the process for reviews was consistent across all prior authorization requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply prior authorization to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying prior authorization to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan(Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: QUANTITY LIMITS
VIRGINIA: STANDARD OPT OUT FORMULARY 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Quantity Limits

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® (hereinafter "PBM" or "Caremark"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Quantity limits (hereinafter sometimes "QL") refers to a limitation that establishes a maximum quantity of a drug that is covered over a specified period of time. In the prescription drug benefit classification, the following materials describe quantity limits:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Prescription drugs covered under this plan are subject to misuse, waste or abuse utilization review by us, your **[provider]** or your network pharmacy. The outcome of the review may include:

- Limiting coverage of a drug to one prescribing **[provider]** or one network pharmacy
- Quantity, dosage or day supply limits
- Requiring a partial fill or denial of coverage]

2. DRUG GUIDE

The Drug Guide provides important information for members pertaining to quantity limits, including the drugs subject to quantity limits and information about exceptions to quantity limit requirements. The most current version is publicly available at:

Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information about drugs subject to quantity limits and exceptions to quantity limit requirements. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. They also describe the medical exception clinical coverage criteria for drugs subject to quantity limits. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies pertain to quantity limits:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management NQTLs (prior authorization, quantity limits, and step therapy) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.
Formulary Development and Management	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.

at CVS Caremark®		
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process, including as applicable for prior authorization requests for exceptions to quantity limits, for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: STANDARD OPT OUT FORMULARY 2025 DRUG GUIDE	
2025_Standard_Opt_Out_Aetna.pdf	
Benefit classifications to which NQTL applies: ✔ **Prescription Drug**	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following section identifies and defines the factors, evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) quantity limit programs; and b) development of coverage criteria. Aetna's PBM, Caremark, maintains standard utilization management (UM) policies that include quantity limits and clinical criteria developed based on nationally recognized clinical guidelines, FDA labeling, and evidence-based literature.

a. Factors for including a drug or drug class in quantity limits programs.

The determination of which drugs are subject to utilization management, including quantity limits, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including quantity limits, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in quantity limits programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Evidence-based Uses and Clinical Efficacy	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Cost Effectiveness	✓	✓

Evidence-based Uses and Clinical Efficacy means: 1) Potentially unsafe and ineffective dose escalation - Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule; Drug or drug class has potential for being prescribed for periods of time exceeding the recommended duration of therapy or when therapy ceases to provide benefit; Drug or drug class has no evidence or data regarding efficacy at doses above the FDA approved limit; Drug or drug class has evidence that increasing the dose past the FDA approved limits does not provide improved efficacy. 2) Dose Optimization - Drug or drug class has evidence that the number of dosage units can be reduced by using a higher strength formulation of the drug without compromising efficacy. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon .The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, including drugs that may be equally efficacious and less costly; 2) High utilization - Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits. An NQTL may be applied to ensure dosing follows the FDA approved limit and is in alignment with the FDA labeled indication(s).The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

b. Factors for the development of coverage criteria

The development of coverage criteria for drugs subject to quantity limits are based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Evidence-based Uses and Clinical Efficacy	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓

Cost Effectiveness	✓	✓

Evidence-based Uses and Clinical Efficacy means: 1) Potentially unsafe and ineffective dose escalation - Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule; Drug or drug class has potential for being prescribed for periods of time exceeding the recommended duration of therapy or when therapy ceases to provide benefit; Drug or drug class has no evidence or data regarding efficacy at doses above the FDA approved limit; Drug or drug class has evidence that increasing the dose past the FDA approved limits does not provide improved efficacy. 2) Dose Optimization - Drug or drug class has evidence that the number of dosage units can be reduced by using a higher strength formulation of the drug without compromising efficacy. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time,

forgetting to take a dose, or stopping the medication too soon. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
    Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, including drugs that may be equally efficacious and less costly; 2) High utilization - Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits. An NQTL may be applied to ensure dosing follows the FDA approved limit and is in alignment with the FDA labeled indication(s). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations

  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

Step 3 sets forth: ***(a)*** *how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL,* ***(b)*** *the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL,* ***(c)*** *as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and* ***(d)*** *as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including quantity limits, and the development of coverage criteria for drugs that require quantity limits, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require quantity limits for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in quantity limits programs and upon which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1)

Evidence-based uses and clinical efficacy; (2) Risk of abuse, misuse, addiction or diversion; (3) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including quantity limits, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs.

The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy
Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a Caremark Medical Director, and by external clinical experts whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology

MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to M/S drugs in the prescription drug benefit classifications. Caremark policies related to quantity limits include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) non-quantitative treatment limitations (NQTLs), to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management (UM) programs.
CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management (UM) programs.

FormDevMgmt.pdf	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the prior authorization process, including as applicable for prior authorization requests for exceptions to quantity limits, for plans subject to Virginia (VA) state laws.

INCLUDING A DRUG OR DRUG CLASS IN QUANTITY LIMITS PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in quantity limits programs and upon which development of coverage criteria are based are: (1) Evidence-based uses and clinical efficacy; (2) Risk of abuse, misuse, addiction or diversion; (3) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in quantity limits programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (prior authorization, step therapy or quantity limits) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary source, must support the coverage conditions of the quantity limits requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard CVS Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within CVS Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply quantity limits to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.
- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The type(s) of NQTL (prior authorization, quantity limit or step therapy) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.
- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.

- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs (including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION- UTILIZATION MANAGEMENT DESIGN PROCESS
DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets

parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.
   v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.
   vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustrative purposes only and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil)

	MH/SUD: Yes **M/S:** No **Therapeutic Category:** Stimulants (Miscellaneous)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • Narcolepsy
	  • Shift Work Disorder (SWD)

Step 3.	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective. Accessed 06-09-25 • Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil). Accessed 06-10-25 ▪ Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy. • Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893. Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil).
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance.
  Accessed 06-09-25

Off-label Prescribing Patterns. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications.
  Accessed 06-09-25

	• Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. ◦ CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.

Step 5	The sources that were used and documented for armodafinil include:
	• Prescribing information for armodafinil (Nuvigil)
	• Drug information Databases and compendia
	  ◦ Lexicomp AHFS DI
	  ◦ Micromedex
	• Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.
	• Summary of Coverage Conditions:
	  ◦ Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  ◦ Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  ◦ Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification

	• Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy. • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil. • Reason for Type of NQTL • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy. • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil): ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days
	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION (INCLUDING QUANTITY LIMITS EXCEPTION REQUESTS)

Caremark performs utilization management on Aetna's behalf. Its policies are used to determine operational aspects of prior authorization. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting prior authorization for both M/S and MH/SUD drugs. This policy documents the requirements for the prior authorization process for plans subject to Virginia (VA) laws. Physicians, patients, or a person appointed to manage the patient's care designated as an authorized representative can request prior authorization or exceptions to quantity limits, and prior authorization requests for exceptions to quantity limits are handled pursuant to this policy which applies equally to MH/SUD and M/S drugs. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.

i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.

i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:

a. Urgent PA Reviews will be completed within 24 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48

hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.

2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.

a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

c. Notification will be provided within 24 hours of making the adverse determination.

3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:

a. Urgent step therapy requests will be completed within 24 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.

b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.

i. If insufficient clinical information is received, CVS Caremark will request the missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;
ii. The reason(s) for the Adverse Determination;
iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;
iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;
v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;
vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.
vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs are subject to quantity limits, the development of coverage criteria, and the process of conducting prior authorization of requests for exceptions to quantity limits, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to quantity limits for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply quantity limits with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used to design and apply quantity limits with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying quantity limits to M/S drugs.

As discussed in Step 4 above, the application of quantity limits within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for quantity limits exception requests are identical across both benefit categories. The operation of the quantity limits process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation comparative analysis is conducted by reviewing the following:

- Prior Authorization/Quantity limits Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – QUANTITY LIMITS EXCEPTIONS

Evaluation of denial rates for M/S and MH/SUD quantity limits exceptions requests is one measure that can evaluate whether quantity limits are applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects quantity limits decisions for MH/SUD and M/S drugs on the **Aetna Standard Opt Out Formulary for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied available through the date of this submission.

Approval/Denial Rates – Quantity Limits Exceptions			
VIRGINIA - Aetna Standard Opt Out Formulary – 2025			
Drug Type	**MED/SURG**	**MH**	**SUD**
Total Requests	133	6	-
Total Approvals	111	6	-
Total Denials	22	-	-
Approval Percent	83.5%	100.0%	0.0%
Denial Percent	16.5%	0.0%	0.0%
Average TAT in Days	0.100	-	-

This data reflects that overall, **100%** of quantity limits exceptions for MH drugs were approved, and **83.5%** of M/S drugs were approved. There were no quantity limits exception requests for SUD drugs. The turnaround time (TAT) for decision making for both MH/SUD drugs and M/S drugs were less than 24 hours. This data reflects that overall, MH/SUD drugs were approved at a higher percentage rate than M/S drugs and the TAT to make a decision was comparable between MH/SUD and M/S drugs.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying utilization management to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its delegate, Caremark, audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or Med Surg condition.
- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:
    - Were correct criteria or guidelines used?
    - Were the criteria questions answered correctly?
    - Was the case decisioned by the appropriate final reviewer?
    - Was the correct decision on the case made based on the applicable clinical criteria?
    - Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria

questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In summary, based upon review of the data and information addressed herein, Aetna may conclude that the processes, strategies, evidentiary standards or other factors used in designing and applying utilization management, including quantity limits, with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying quantity limits with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its Pharmacy Benefit Manager, Caremark, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Quantity limits refers to a limitation that establishes a maximum quantity of a drug that is covered over a specified period

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to utilization management including quantity limits, and the development of coverage

criteria for drugs that require quantity limits, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of quantity limits. As noted in **Step 3**, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to quantity limits and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to quantity limits in a comparable manner, and the MH/SUD drugs to which quantity limits applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that quantity limits are designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4,** as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to quantity limits, the development of coverage criteria for drugs that require quantity limits, and the process of conducting prior authorization for quantity limits exception requests. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply quantity limits. That analysis shows that no separate policies or procedures exist with respect to quantity limits for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying quantity limits in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, quantity limits are designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and are not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, quantity limits are applied in a comparable manner for both M/S and MH/SUD drugs. The application of quantity limits within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs.

Further, the operational procedures for quantity limits are identical across both benefit categories. The operation of the prior authorization process for quantity limits demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of quantity limits approval and denial rates, which demonstrated lower rates of denial for MH/SUD drugs as compared to M/S drugs and the turnaround time for decision making for both MH/SUD and M/S drugs was less than 24 hours. Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating to utilization management coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases demonstrated that the process for reviews was consistent across all utilization management requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply quantity limits to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying quantity limits to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan (Aetna) • CVS Caremark® (Delegate)

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NONQUANTITATIVE TREATMENT LIMITATION (NQTL) COMPARATIVE ANALYSIS

PRESCRIPTION DRUG BENEFIT CLASSIFICATION
UTILIZATION MANAGEMENT: STEP THERAPY
VIRGINIA: STANDARD OPT OUT FORMULARY – AETNA 2025

Step 1: Description of the NQTL

Step 1 provides a description of the NQTL in two parts: ***(1)*** *an identification and description of the NQTL and* ***(2)*** *an identification of all mental health or substance use disorder ("MH/SUD") and medical/surgical ("M/S") benefits to which the NQTL applies and a description of the benefits classifications to which the MH/SUD and M/S benefits subjected to the NQTL belong.*

Step 1, Part 1. Identification of the NQTL: Utilization Management: Step Therapy

Aetna delegates the administration of its prescription drug benefit to its Pharmacy Benefit Manager, CVS Caremark® (hereinafter sometimes "PBM" or "Caremark"), including utilization management for prescription drugs. Utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Step Therapy (hereinafter sometimes "ST") refers to criteria that define the circumstances under which a drug requiring prerequisite therapy will be systematically paid under a prescription benefit or reviewed through the prior authorization process. For MH/SUD and M/S drugs subject to a step therapy requirement, prior authorization is required. Prior authorization of prescription drugs subject to a step therapy requirement is conducted by the Caremark Prior Authorization Department using pre-established medical necessity guidelines developed by Caremark. In the prescription drug benefit classification, the following materials describe step therapy:

1. PLAN DOCUMENTS

Certificate of Coverage: HCOC 13 SERFF# AETN-134117030

Step therapy is a type of **precertification** where you must try one or more prerequisite drugs before a step therapy drug is covered. A 'prerequisite' is something that is required before something else. Prerequisite drugs are FDA-approved, may cost less and treat the same condition. If you don't try the prerequisite drugs first, the step therapy drug may not be covered.

Contact us or go online to get the most up to date **precertification** requirements and list of step therapy drugs.

2. DRUG GUIDE

The Drug Guide includes important information for members pertaining to step therapy, including identification of M/S and MH/SUD medications requiring step therapy. The most current version is publicly available at:

Find a Medication: Prescription Drug List (Formulary), Coverage & Costs | Aetna

3. PROVIDER MANUAL

The Provider Manual includes pharmacy benefit plan and drug formulary information for providers/prescribers, including information pertaining to step therapy. The most current version is publicly available at: Aetna Provider Manual

4. PHARMACY CLINICAL POLICY BULLETINS (PCPBS)

Pharmacy clinical policy bulletins (PCPBs) are used as a guide when determining coverage for members with benefits plans that cover outpatient prescription drugs. Pharmacy Clinical Policy Bulletins can be found on Aetna's website here: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/pharmacy-clinical-policy-bulletins.html

5. POLICIES AND PROCEDURES

Aetna delegates the administration of its prescription drug benefit (prescription drug) to its PBM, Caremark, including utilization management for prescription drugs. The following Caremark policies describe step therapy:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs utilization management (UM) NQTLs (prior authorization, step therapy, quantity limits) to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management programs.

CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the utilization management process for plans subject to Virginia (VA) state laws.

Step 1, Part 2. Applicable M/S and MH/SUD Benefits

In the **Prescription Drug** benefit classification, the drug guide below contains MH/SUD and M/S prescription drugs covered under the prescription drug benefit that are subject to Prior Authorization, Step Therapy and Quantity Limits.

VIRGINIA: STANDARD OPT OUT FORMULARY 2025 DRUG GUIDE	
2025_Standard_Opt_Out_Aetna.pdf	
Benefit classifications to which NQTL applies: ✔ Prescription Drug	
M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
▪ Prescription Drugs used for Medical/Surgical treatment.	▪ Prescription Drugs used for MH or SUD treatment.

Step 2: Identification and Definition of the Factors and Evidentiary Standards Used to Design or Apply NQTL

Step 2 sets forth, with respect to every factor considered or relied upon to design or apply the NQTL:(a) identification of every factor considered or relied upon, as well as the evidentiary standards and sources considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived in determining which MH/SUD and M/S benefits are subject to the NQTL, and (b) definition of every factor, including a detailed description of the factor and a description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard).

The following identifies and defines the factors, and the accompanying evidentiary standards and sources considered or relied upon in the design or application of the NQTL for: (a) including a drug or drug class in step therapy programs; and b) development of coverage criteria. Caremark develops standard formularies and assigns utilization management designations such as prior authorization, step therapy, and quantity limits based on clinical, safety and cost-effectiveness factors supported by nationally recognized evidence and guidelines.

(a) Factors for including a drug or drug class in step therapy programs.

The determination of which drugs are subject to utilization management, including step therapy, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to apply utilization management, including step therapy, to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. The following factors support the inclusion of a drug or drug class in step therapy programs:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a

drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2)Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label

- FDA Online Label Repository
- FDA Drug Safety-related Labeling Changes (SrLC)
- FDA Drug Trial Snapshot
- Disease specific Clinical Practice Guideline Protocols
- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR), Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols

- Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
- AHFS Drug Information and/or Lexi-Drugs
- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical evidence determined to be experimental, investigational or unproven
  - Clinical Practice Guidelines
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong

time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
  - CVS Caremark® Drug Trend Report
  - Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**

- CMS.gov
- Individual state regulations sites
- Health and Human Services (HHS.gov)
- Healthcare.gov
- NCQA.org
- URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts

- Internal business partner consultation

(b) Factors for the development of coverage criteria

The development of coverage criteria for drugs that require step therapy is based on the following factors:

Factor	Applicable to M/S	Applicable to MH/SUD
Safety Considerations	✓	✓
Evidence-based Uses and Clinical Efficacy	✓	✓
Patient Population/Monitoring Considerations/Treatment Complexity	✓	✓
Off-label Prescribing Patterns	✓	✓
Risk of abuse, misuse, addiction or diversion	✓	✓
Regulatory and/or Accreditation Requirements	✓	✓
Cost Effectiveness	✓	✓

Safety Considerations means: 1) Drug or drug class has safety considerations, evidence of harm, unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient's safety; 2) Drug or drug class has been shown in clinical literature or other clinical evidence to be used at a higher dose than deemed safe and effective because it provided temporary relief of a progressive condition or has a complex titration schedule. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology

- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- High Risk Medication in the Elderly Polypharmacy Guidelines

Evidence-based Uses and Clinical Efficacy means: 1) Drug or drug class is efficacious for treatment within the intended treatment population, accepted sequential drug use or concurrent drug use and there is no clinical evidence to support its efficacy outside of the intended population or outside of the sequential drug use. An NQTL will be applied to confirm appropriate treatment population or place in therapy; 2)Drug or drug class requires specific laboratory values or tests to confirm the FDA approved indication; 3) Drug or drug class requires confirmation that the patient is responding to therapy via patient monitoring. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Patient Population/Monitoring Considerations/Treatment Complexity means: 1) Drug or drug class has restrictions to populations with certain specific characteristics or attributes (e.g., age, sex, diagnoses, comorbidities, site of care, treatment naïve vs. experienced); 2) Drug or drug class has potential for use in sub-populations of patients which have been shown not to benefit from therapy. (e.g., Grastek, Ragwitek, Vectibix/Erivedge (KRAS testing), Tarceva (EGFR),

Zelboraf/Tafinlar/Mekinist (BRAF), Herceptin (HER2), Kalydeco). An NQTL will be applied to restrict coverage to those populations shown to benefit from treatment; 3) Drug or drug class requires care coordination and/or additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, or other standard non-drug supportive therapies.); 4) Drug or drug class requires special laboratory monitoring and/or a specific physician specialty to treat; 5) Drug or drug class is used to treat a rare condition; 6) Drug or drug class has evidence for waste or unnecessary use when a drug needs frequent dose adjustments, when it is available in multiple strengths, or when it may need a dose titration. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Off-label Prescribing Patterns means: 1) Drug or drug class has shown the physician practice of prescribing the drug for a purpose other than one of the indications for which the product is approved by the FDA; 2) Drug or drug class has excessive use concerns and has been shown in clinical evidence to be used beyond the FDA-approved dosage and administration guidelines (e.g., excessive quantities or as a first line agent outside of product labeling). The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information

- Clinical evidence determined to be experimental, investigational or unproven
- Clinical Practice Guidelines
- Consultation with an External Clinical Expert for addressing complex or chronic conditions for assessing expertise in specific areas of medicine. (Ex: cardiologist, neurologist, endocrinologist, etc.)

- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
  - Drug specific consult with external clinical expert

Risk of abuse, misuse, addiction or diversion means: 1) Drug or drug class has evidence of abuse or dependency which may include taking the incorrect dose, taking a dose at the wrong time, forgetting to take a dose, or stopping the medication too soon; 2) Drug or drug class has potential for being prescribed in quantities exceeding the recommended dosing regimens. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - FDA drug approvals and databases with drug specific product information
  - Clinical Practice Guidelines
  - Drug information databases/Compendia
  - Drug Trend Reporting
  - U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA)
- **Sources:**
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Safety-related Labeling Changes (SrLC)
  - FDA Drug Trial Snapshot
  - Disease specific Clinical Practice Guideline Protocols
  - Internal CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs- Level of Evidence
  - AHFS Drug Information and/or Lexi-Drugs

- Micromedex DRUGDEX® (IBM Watson Health)
- Clinical Pharmacology
- Medline (PubMed)
- Up To Date drug database
- Diagnostic and Statistical Manual of Mental Disorders: 5th Editions (DSM5)
- Centers for Medicare and Medicaid Services (CMS) Quarterly Drug Trend Analysis
- CVS Caremark® Drug Trend Report
- Treatment Improvement Protocol (TIP) Series 43. Medication Assisted treatment for Opioid Addiction in Opioid Treatment Programs.

Regulatory and/or Accreditation Requirements means: NQTL may be applied when a specific regulatory or accreditation requirement mandates or explicitly supports utilization controls for a drug or drug class. Utilization restrictions must align with applicable legal requirements and are not imposed when explicitly barred by regulation. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Federal Regulations
  - Individual State Regulations
  - Accreditation Resources
- **Sources:**
  - CMS.gov
  - Individual state regulations sites
  - Health and Human Services (HHS.gov)
  - Healthcare.gov
  - NCQA.org
  - URAC.org

Cost-effectiveness: *Cost considerations are only applied where clinically appropriate and consistently used for both MH/SUD and M/S drugs. Cost -effectiveness means: 1) Multiple drugs exist to treat a given condition, and at least one option is therapeutically equivalent and available at a lower cost; 2) Drug or drug class has a generic drug and/or therapeutic alternative available that is clinically appropriate and more cost-effective based on published literature, clinical guidelines, or internal cost effectiveness analysis; 3) A drug or drug class is available in multiple dosage forms and a lower-cost dosage form may be selected when clinical equivalence is established; 4) (High utilization) Drug or drug class carries multiple (2 or more) indications for highly prevalent disease state(s) that affects a large portion of the population and has clinical evidence to be overused, used off-label or carries safety risks when used outside of FDA approved indications or limits; An NQTL may be applied for any of the following conditions: a. To collect additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population

and to confirm patient response to therapy; b. To adhere to clinical guidelines and/or when lower cost alternatives (often generic medications) are used before moving to the higher cost option. The **evidentiary standards and sources** upon which this factor is based are:

- **Evidentiary Standards:**
  - Approved Drug Products with Therapeutic Equivalence Evaluations
  - FDA drug approvals and databases with drug specific product information
  - Drug information databases/Compendia
  - Internal Business or Trade strategy
- **Sources:**
  - FDA Orange Book
  - FDA Purple Book
  - FDA Drug-specific product label
  - FDA Online Label Repository
  - FDA Drug Trial Snapshot
  - AHFS Drug Information and/or Lexi-Drugs
  - Micromedex DRUGDEX® (IBM Watson Health)
  - Clinical Pharmacology
  - Medline (PubMed)
  - Up To Date drug database
  - CVS Caremark® Drug Claims Utilization
  - Manufacturer Agreements or Rebate Contracts
  - Internal business partner consultation

Step 3: Description of How Factors are Used in the Design or Application of NQTL

*Step 3 sets forth: **(a)** how the factors identified in Step 2 are used to determine which MH/SUD and M/S benefits are subject to the NQTL, **(b)** the evidentiary standards considered or relied upon in designing or applying the factors, or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL, **(c)** as applicable, how a factor applies to the nature of decisions made in the administration of benefits, the timing of the decisions, and the professional designation and qualification of the decisionmakers, and **(d)** as applicable, any deviations from a factor, its applicability, or its definition to apply the NQTL to MH/SUD or M/S benefits. Furthermore, this sub-part includes an explanation of the inter-relationship of the factors identified in Step 2.*

The determination of which M/S and MH/SUD drugs are subject to utilization management including step therapy, and the development of coverage criteria for drugs that require step therapy, are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to require step therapy for a drug or drug class, and to develop coverage criteria, are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. As set forth above, in step 2, the factors that support inclusion of a drug or drug class in step therapy programs and upon

which development of coverage criteria is based, for both M/S and MH/SUD drugs are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness.

The factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement utilization management, including step therapy, would be met if any one factor applies to the drug. There is no deviation or variation from these factors, their applicability, or their definitions, as they apply in the same way to MH/SUD and M/S drugs. The following teams and committees within Caremark play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee. The same committees participate in the evaluation of both M/S and MH/SUD drugs:

- The UM Clinical Development team drafts utilization management NQTL requirements (prior authorization, step therapy, and quantity limit) that include coverage for use supported by evidence-based medicine and standard of care sources.

Utilization Management Clinical Development Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists Clinical Pharmacists, Analysts

- The Formulary Review Committee (FRC) reviews utilization management NQTLs (prior authorization, step therapy, and quantity limits) for Caremark® template formularies prior to review and approval by the P&T Committee.

Formulary Review Committee (FRC)

Makes business recommendations, and includes individuals with expertise in pharmacy benefit management.

Job Title - Credential	Business Unit
Director Chairperson - voting	Trade Relations
VP, Pharmacist - voting	Product Development - Sales
Exec Director, MBA - voting	Finance
Exec Director, MBA - voting	Trade Relations
VP, Pharmacist	Medical Affairs - Clinical Oversight
Medical Director, MD Family Medicine, MBA	Medical Affairs
Director	Formulary Administration
SVP, JD, MBA	Legal
Exec Director, RN	Formulary Administration
Exec Director, Pharmacist	Medicare Gov Pharmacy

Lead Director, Pharmacy Technician	Project Program Management

- Standard UM NQTLs (prior authorization, step therapy and quantity limits) are reviewed internally by a CVS Caremark Medical Director, and by external clinical experts. whose participation is coordinated through the Caremark Clinical Program Oversight (CPO) review process.

Medical Directors

Job Title - Credential
VP Medical Affairs, MD
Exec Medical Director, MD
Sr. Medical Directors, MD
Medical Directors, MD
Medical Directors, DO

Clinical Program Oversight (CPO) Department

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

- The P&T Committee reviews and approves the clinical criteria used in the application of UM NQTLs (prior authorization, step therapy and quantity limits).

P&T Committee

An external advisory body of experts composed of 21 independent health care professionals, including 18 physicians, two pharmacists, and one patient representative who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Consideration for membership on the committee is based upon active involvement in clinical practice, national recognition in their field, contributions to medical and/or pharmacy literature, and previous experience with pharmacy and therapeutics committees. The Committee members are identified by recommendations from other Committee members and internal Medical Affairs Physician Leadership. All Committee members initially have their credentials verified and then undergo an annual credentialing review.

Voting Members Board Certified Specialty	
Medical Doctor (MD) – Allergy	MD – Hematology/Oncology
MD – Cardiology	MD – Internal Medicine
Doctor of pharmacy (PharmD)	MD – Infectious Disease
MD – Dermatology	MD – Medical Ethicist
MD – Endocrinology	MD – Neurology

MD – Family Practice	MD – Oncology
MD – Gastroenterology	MD – Pediatrics
PharmD – Gerontology	MD – Pediatrics
PharmD – Gerontology	MD – Pharmacoeconomics
MD – Gerontology	MD – Psychiatry
MD – Gerontology	MD – Rheumatology
MD – Hematology/Oncology	Patient Representative

Step 4: Demonstration of Comparability and Stringency, As Written

Step 4 demonstrates that, under the terms of the plan, as written, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL with respect to M/S benefits.

This section demonstrates that, as written, the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to M/S drugs in the prescription drug benefit classifications. Caremark policies related to step therapy include:

Document #	Title	Description
DOC-095057	CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA)	This policy outlines the process by which the PBM designs UM NQTLs (prior authorization, step therapy, quantity limits), to demonstrate that UM strategies are clinically justified, consistently applied across prescription drug classifications, and consistent with applicable mental health parity requirements, including the Mental Health Parity and Addiction Equity Act (MHPAEA).
CPS-0165	CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence	This policy outlines the minimal levels of evidence required for inclusion of accepted uses of drugs within the standard CVS Caremark Utilization Management programs.

CPS-0006	CVS Caremark® Utilization Management Criteria Development and Maintenance	This policy describes the development and maintenance of standard Utilization Management programs.
Formulary Development and Management at CVS Caremark®	Formulary Development and Management at CVS Caremark®	This document provides information regarding the Caremark Pharmacy & Therapeutics Committee (P&T) Committee, and other Caremark groups involved with the development and management of drug formularies.
DOC-049152	Prior Authorization Process (Virginia)	This policy and procedure documents the requirements for the utilization management process for plans subject to Virginia (VA) state laws.

INCLUDING A DRUG OR DRUG CLASS IN STEP THERAPY PROGRAMS AND DEVELOPMENT OF COVERAGE CRITERIA

As set forth in Step 2 above, the factors that support inclusion of a drug or drug class in step therapy programs and upon which development of coverage criteria is based are: (1) Safety considerations; (2) Evidence-based uses and clinical efficacy; (3) Patient population/monitoring considerations/treatment complexity; (4) Off-label prescribing patterns; (5) Risk of abuse, misuse, addiction or diversion; (6) Regulatory and/or accreditation requirements; and (7) Cost-Effectiveness. Each of these factors, and the sources and evidentiary standards identified in Step 2, are documented in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** which applies equally to M/S and MH/SUD drugs.

As written in the above-referenced policy, the factors, evidentiary standards, and sources identified in Step 2 are used to determine MH/SUD and M/S drugs for inclusion in step therapy programs and development of coverage criteria. The determination of which drugs are subject to utilization management are based upon the same strategies and processes regardless of therapeutic category. Factors considered in the determination to assign an NQTL (step therapy, quantity limits, prior authorization) to a drug or drug class are applied consistently across all drug categories and are used without regard to whether the medications treat MH/SUD disorders or M/S conditions. Evidentiary standards are applied consistently across MH/SUD and M/S drugs and conflicting sources are resolved through clinical review and documented rationale.

With respect to the development of coverage criteria, a sufficient level of evidence (as defined in Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence), demonstrated by inclusion of at least one evidentiary

source, must support the coverage conditions of the step therapy requirement and include coverage for uses supported by evidence-based medicine and generally accepted standards of care. Conflicting sources are resolved through clinical review and documented rationale. In the instance of conflicting information, Caremark assesses consistency across identified reputable sources per Policy CPS-0165 considers coverage of all supported indications, and/or considers incorporation of clinical context and standard practice through the engagement of subject matter experts (internal medical directors, external clinical consultant) to determine appropriate criteria for coverage to support the preponderance of evidence.

As written, **Policy CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence,** describes the levels of evidence required for the development of standard utilization management criteria, including prior authorization, step therapy and quantity limits. All standard Caremark Utilization Management Criteria include US Food and Drug Administration (FDA)-approved Indications and Off-label Uses of drugs and drug products that are sufficiently supported by evidence-based medicine, as defined pursuant to the policy. Additionally, the dosage for drugs must be supported by FDA-approved labeling, standard pharmacy compendia, evidence-based guidelines, or well-designed controlled clinical trials in peer-reviewed published medical literature. The standards set forth in this policy apply equally to MH/SUD and M/S drugs. The sources and evidentiary standards used are different for each drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with Caremark® policies.

Policy CPS-0006 Title: CVS Caremark® Utilization Management Criteria Development and Maintenance, describes the development and maintenance of standard Utilization Management programs, including clinical development and clinical program oversight within Caremark and applies to both M/S and MH/SUD drugs equally. The policy provides an overview of the procedures, departments and committees involved in the initial and periodic evaluation of M/S and MH/SUD drugs, and the development of medical necessity criteria where applicable, when a decision is made to apply step therapy to a drug.

As outlined in **Policy 095057 CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA),** for both M/S and MH/SUD drugs, the following process applies:

- Step 1- Drug Identification: A new or existing drug is selected based on annual policy review or FDA approval.
- Step 2 – NQTL Application Evaluation: The drug is evaluated for the application of UM by an internal clinical group, including a pharmacist and medical director, using the defined factors in this policy. Factors are considered without a prescribed hierarchy. All the factors are reviewed in no particular order to determine if it would apply to the identified drug. The decision to implement UM would be met if any one factor applies to the drug. The

type(s) of NQTL (prior authorization, step therapy, quantity limits) to implement is determined by the factor(s) that apply to the drug as supported by clinical evidence.

- Step 3 - Drafting of Coverage Conditions (Clinical Criteria): A pharmacist drafts proposed coverage conditions based on the appropriate factors and evidentiary standards and sources to support those factors. A UM writer will perform a deeper clinical review of the evidentiary standards to ensure all coverage conditions being applied are clinically appropriate.
- Step 4- Internal Clinical Review: The draft criteria are reviewed by the UM Leadership team and internal medical directors to ensure clinical appropriateness and compliance.
- Step 5 - External Review and P&T Committee Approval: Once internally vetted, the proposed NQTL criteria are reviewed by an external clinical expert and reviewed for approval by the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee.
- Step 6 - Finalization and Publication: Following approval, finalized criteria are published and distributed to stakeholder groups and account teams, for implementation.

All active NQTLs are reviewed for clinical appropriateness at least annually or more frequently if new information becomes available that impacts the basis for coverage. The annual review will be conducted by all of the following:

- A Clinical Development pharmacist
- Internal Medical Affairs Review consisting of an internal physician
- An External Clinical Expert who is an actively practicing physician or pharmacist and who has current knowledge relevant to the drug/condition being treated.
- CVS Caremark National Pharmacy and Therapeutics (P&T) Committee members.

As explained pursuant to the **Formulary Development and Management at CVS Caremark®** document, Caremark's P&T Committee is an external advisory body of experts from across the United States, composed of 21 independent health care professionals, including 18 physicians, 2 pharmacists, and one patient representative. All P&T Committee members have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the P&T Committee members are actively practicing physicians and pharmacists. Two physicians and two pharmacists are experts in the care of the elderly or disabled. One of the physicians on the committee is a medical ethicist. The medical ethicist facilitates discussion as needed and provides unbiased feedback with respect to the logic and appropriateness of the conclusions drawn from the discussions and the decisions that are reached. The composition of the P&T Committee exceeds the CMS P&T Committee requirements for Medicare Part D sponsors and exceeds URAC standards. As set forth above in Step 3, the physician membership includes psychiatry representation. The CVS Caremark National P&T Committee will review and approve for clinical appropriateness coverage criteria, treatment protocols and procedures, and all other clinical parameters of the CVS Caremark and Aetna formulary and utilization management programs

(including drug utilization review, step therapies, quantity limits, formulary exceptions and other drug utilization activities that affect access).

PARITY COMPLIANCE EVALUATION-
UTILIZATION MANAGEMENT DESIGN PROCESS DRUG LEVEL COMPARISON

As described in CVS Caremark® DOC-095057, CVS Caremark® Approach for Compliance with The Mental Health Parity and Addiction Equity Act (MHPAEA), Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed.

a. The following is utilized and documented in these reviews:
   i. Factors considered: A list of factors used in the NQTL's (PA, ST, QL) development, with justification for each.
   ii. Applicable NQTL types: Identification of each type of NQTL (e.g., PA, ST, QL) applied to the drug or drug class.
   iii. Evidentiary Standards and Sources: All supporting evidence (e.g., clinical guidelines, compendia, etc.) used to support each factor must be documented.
   iv. Findings and Conclusions: Written rationale linking each factor to an applied NTQL.
   v. A detailed explanation of any differences between MH/SUD and M/S applications, including documentation of stringency or weight variations if applicable.

b. Methodology for Ensuring Consistent Application Across Drugs:
   i. Step 1: A new or existing drug is identified upon annual review or FDA product approval.
   ii. Step 2: The FDA product label is accessed to document drug-specific information such as FDA approved indications, safety considerations, efficacy data, any patient demographics defined in the product label, laboratory or clinical monitoring information, drug administration guidelines, abuse potential, etc.
   iii. Step 3: Each factor is evaluated using the evidentiary standards and sources defined in this policy. A rationale for why the factor was used or not used will be documented along with any relationship or interactions of the factors and the order that the factors were applied (if applicable.)
   iv. Step 4: The weighting of the factors will be evaluated during this comparative analysis and any deviations or variations of the weight of the factor was applied to the NQTL. If any deviations or variations are found in this review, an explanation/rationale will be documented.
   v. Step 5: Evidence Capture: All evidence used to support a factor's inclusion is captured and documented for each NQTL type applied.

vi. Step 6: A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented

The following section illustrates how this process is applied in practice using a representative drug. This example is for illustration only, and demonstrates the consistent application of the process across therapeutic classes.

Step	Mental Health/Substance Use Disorder Drug
Step 1	Armodafinil was identified as an existing drug for which UM is under evaluation. **Drug Name:** armodafinil (Nuvigil) **MH/SUD:** Yes **M/S:** No **Therapeutic Category:** Stimulants (Misc.)

Step 2	UM writer pulled FDA product label for armodafinil and documented the approved indications for the drug. The approved FDA indications for armodafinil include
	• To improve wakefulness in adult patients with excessive sleepiness associated with:
	  • Obstructive Sleep Apnea (OSA)
	  • NarcolepsyShift Work Disorder (SWD)

Step 3.	UM writer evaluated all factors using the evidentiary standards and sources. The factors that applied to armodafinil include: **Safety Considerations** - the prescribing information for armodafinil lists multiple warnings and precautions, requiring consideration for patient safety. Armodafinil is a Schedule IV controlled substance. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe use. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) lists multiple warnings and precautions, adverse reactions, and drug interactions. Per the prescribing information, armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates warnings and precautions and adverse reactions that are within the prescribing information. Lexicomp states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 • Micromedex - Micromedex includes warnings and precautions and adverse reactions that are within the prescribing information. Micromedex provides more details regarding drug interactions compared to the prescribing information, including, but not limited to the severity of the interaction, onset, and clinical management. Accessed 06-10-25 **Evidence-based Uses and Clinical Efficacy** - The effectiveness of armodafinil (Nuvigil) in improving wakefulness in patients with excessive sleepiness associated with OSA, narcolepsy or SWD was established in drug trials prior to FDA approval. UM is applied to gather additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based effective use. Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) is used to determine the drug's evidence-based uses.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information obtained from product label by providing the evidence-based uses for armodafinil (Nuvigil) and additional clinical perspective.
  Accessed 06-09-25
- Micromedex - Micromedex validates the information obtained from previous sources and provides evidence-based uses for armodafinil (Nuvigil).
  Accessed 06-10-25

- Clinical Practice Guidelines – The clinical practice guideline establishes need for continued follow-up to assess treatment efficacy.
- Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
  Accessed 06-10-25

Patient Population/Monitoring Considerations/Treatment Complexity – Armodafinil is indicated to improve wakefulness in adult patients with excessive sleepiness due to OSA, Narcolepsy or SWD and should be restricted to the adult patient population. According to clinical practice guidelines, this drug requires the use of diagnostic testing and follow-up testing as well as multidisciplinary management.

Sources reviewed for this factor:

- Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil lists the age restriction within the FDA approved indication.
  Accessed 06-09-25
- Lexicomp AHFS DI - Lexicomp validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-09-25
- Micromedex - Micromedex validates information that was found in previous sources and provides the age restriction for armodafinil which can be found within the prescribing information.
  Accessed 06-10-25
- Clinical Practice Guidelines - Clinical Practice Guidelines provide comprehensive information regarding the disease state, diagnostic criteria, non-pharmacological treatment options, and patient monitoring.
- 1. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
  Accessed 06-10-25
- 2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clin Sleep Med. 2009:5(3):263-276.
  Accessed 06-10-25
- 3. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
  Accessed 06-10-25
- 4. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
  Accessed 06-10-25
- 5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.
  Accessed 06-10-25

Risk of Abuse, Misuse, Addiction or Diversion- Armodafinil is a Schedule IV controlled substance, thus evidence of abuse or dependency which may include taking the incorrect dosing.

	Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) states that armodafinil (Nuvigil) is a Schedule IV controlled substance and that abuse and dependence are evident with armodafinil (Nuvigil). Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp validates information found in prescribing information and states that armodafinil (Nuvigil) is a Schedule IV controlled substance. Accessed 06-09-25 **Off-label Prescribing Patterns**. - Armodafinil is subject to physician practice of prescribing for purposes other than one of the indications for which the product is approved by the FDA. Sources reviewed for this factor: • Prescribing information for armodafinil (Nuvigil) - The prescribing information for armodafinil (Nuvigil) provides the FDA approved indications. Accessed 06-09-25 • Lexicomp AHFS DI - Lexicomp AHFS DI provides uses which are FDA approved as well as other uses which may be considered off label. Lexicomp confirms that armodafinil (Nuvigil) is used for FDA indications only. Accessed 06-09-25 • Micromedex - Micromedex provides FDA approved uses as well as non-FDA approved uses with a 'Recommendation' and 'Strength of Evidence' to outline off label uses. For armodafinil (Nuvigil), non-FDA approved uses are listed, but the recommendation and strength of evidence are not sufficient and do not meet our Level of Evidence (LOE) policy. Accessed 06-10-25 • Clinical Practice Guidelines - Clinical Practice Guidelines provide the minimal levels of evidence required for inclusion of accepted uses of drugs to be used within the standard Utilization Management (UM) programs. • CVS Caremark® Policy: CPS-0165 CVS Caremark® Utilization Management and Drug Utilization Review Programs - Levels of Evidence The factors that did not apply to armodafinil include: • **Cost-Effectiveness** factor did not apply due to the limited options available to treat the conditions for which armodafinil are indicated. • **Regulatory and/or Accreditation Requirements** did not apply since there are no specific mandates identified.
Step 4	The factors were evaluated in no particular order. Generally, factors are given equal weight unless justified otherwise. In this evaluation, cost was given less or no weight due to the limited treatment options available to treat the patient population, and regulatory requirements were not assigned weight, as no applicable mandates were identified.

Step 5	The sources that were used and documented for armodafinil include:
	• Prescribing information for armodafinil (Nuvigil)
	• Drug information Databases and compendia
	  • Lexicomp AHFS DI
	  • Micromedex
	• Clinical Practice Guidelines

Step 6	A summary of NQTL Justification: The coverage conditions for all NQTLs, a UM justification for why the NQTL was applied and the reason for the type of NQTL that was applied will be documented.

	• Summary of Coverage Conditions:
	  • Narcolepsy:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Obstructive Sleep Apnea:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Use of non-pharmacological therapies prior to start of medication and continuation after is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Ongoing monitoring of response required for continued coverage
	  • Shift Work Disorder:
	  ▪ Diagnosis is required
	  ▪ Specific test to confirm diagnosis is required
	  ▪ Must be prescribed by, or in consultation with, a sleep specialist
	  ▪ Symptoms must be present for a certain period of time prior to initiation of therapy
	  ▪ Ongoing monitoring of response required for continued coverage
	• Summary of UM Justification
	  • Due to the necessity for evidence-based appropriate use, population-specific restrictions and laboratory monitoring, and patient monitoring for treatment response, Prior Authorization (PA) was applied to armodafinil to ensure evidence-based drug use within the intended treatment population and to confirm patient response to therapy.
	  • Due to the risk of abuse, misuse, and diversion along with safety considerations, there is a need to ensure doses do not exceed the FDA approved dosing. Therefore, a Quantity Limit was applied to armodafinil.
	• Reason for Type of NQTL
	  • A prior authorization was applied to the drug in order to allow collection of additional information which is not ordinarily available from the prescription claim transaction process to ensure evidence based safe and effective use within the intended treatment population and to confirm patient response to therapy.
	  • A quantity limit was applied to ensure dosing is consistent with the FDA approved limit and is in alignment with the FDA labeled indication. The following quantity limits were applied to armodafinil (Nuvigil):
	  ▪ Nuvigil (armodafinil) 50mg: 60 tablets/25 days OR 180 tablets/75 days
	  ▪ Nuvigil (armodafinil) 150mg, 200mg, 250mg: 30 tablets/25 days OR 90 tablets/75 days

	Factor Application Statement: The application of factors, sources, and evidentiary standards was conducted using a consistent methodology across all drugs evaluated. Any discrepancies in the use of sources or application of factors were reviewed and, where applicable, explained in accordance with the parity requirements outlined under MHPAEA. Documentation reflects adherence to the comparability and stringency standards for non-quantitative treatment limitations.

THE PROCESS OF CONDUCTING PRIOR AUTHORIZATION (INCLUDING FOR MH/SUD AND M/S DRUGS THAT REQUIRE STEP THERAPY)

Caremark performs utilization management on behalf of Aetna. Its policies are used to determine operational aspects of prior authorization conducted for drugs that require step therapy. These processes are described in detail in **CVS Caremark® DOC-049152 Prior Authorization Process (Virginia**), which applies equally to conducting reviews for M/S and MH/SUD drugs, including drugs that have a step therapy requirement. This policy documents the requirements for

the prior authorization process, including for step therapy, for plans subject to Virginia (IN) laws. Consistent with this policy, the program provides a reliable process to ensure clinically appropriate drug usage, within the limits of a specific plan benefit. All review requests are processed accurately and in a timely manner in compliance with state and federal regulations and without regard to whether the medication is used to treat MH/SUD or M/S conditions or diseases. Specifically, the following process applies:

General Procedure

The provider is able to submit a PA request electronically, by phone, fax, or in writing.

a. Fax requests can be sent into the PA Department toll-free fax number.
    i. The standard criteria forms are available online at www.Caremark®.com or can be requested via the toll-free automated phone system.

b. Phone requests can be initiated by the doctor's office calling the PA Department toll-free phone number.
    i. CVS Caremark® will accept requests 24 hours a day and render all Urgent Review decisions within the regulatory timeframe allowed.

    ii. Plan Members can also initiate a PA request by calling Customer Care.

c. Electronic requests are submitted using the ePA system.

    i. ePA allows a provider to access the PA process through an online or e-prescribing tool.

    ii. The system follows the proposed National Council of Prescription Drug Programs ePA transaction set to allow for the communications of the PA request and response process.

    iii. The provider will access and answer the criteria questions electronically. The algorithms for PA evaluation and the documentation within our PA systems do not change with ePA.

    iv. Requests submitted via ePA will be decided based on the information provided with the request.

d. Written requests can be mailed to the CVS Caremark® Prior Authorization Department.

Prior Authorization Approvals

Decision to approve a PA request will be made by a system algorithm after receiving data electronically or after a Representative manually enters data that is clear and does not require a nurse or pharmacist review. If any data on the PA request is unclear, the request will be forwarded to a nurse or pharmacist for further review. Approvals can also be determined by a licensed pharmacist, nurse, or a physician reviewer upon clinical review. Any request that does not meet an approval scenario based on system algorithm is forwarded to a pharmacist for a clinical review.

Prior Authorization Denial or Adverse Action

Decision to deny a PA request or to authorize a service in an amount, duration, or scope that is less than requested will be made by a physician.

Timeframes for Prior Authorization Determinations

1. The PA Department will make a determination and give written notice to the provider and Member regarding the determination as fast as the Plan Member's condition requires and no more than:
    a. Urgent PA Reviews will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent PA Reviews will be completed within two (2) business days from receipt of all information necessary to complete the Review.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within two (2) business days of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within two (2) business days from receipt of completed information or the end of the period afforded to provide the specified information.
2. The PA Department will make a determination and give notice to the Provider and Member regarding the determination of a prescription drug that alleviates cancer pain within 24 hours following the request for coverage.
    a. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
    b. CVS Caremark will make a determination within the earlier of 24 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    c. Notification will be provided within 24 hours of making the adverse determination.
3. The PA Department will make a determination and give notice to the provider and Member regarding the determination for step therapy requests within the following timeframes:
    a. Urgent step therapy requests will be completed within 24 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the missing information within 24 hours of receipt of request and allow at least 48 hours for provider to submit.
        ii. CVS Caremark will make a determination within the earlier of 48 hours of receipt of necessary information or the end of the period afforded to provide the specified information.
    b. Non-Urgent step therapy requests will be completed within 72 hours from receipt of request.
        i. If insufficient clinical information is received, CVS Caremark will request the

missing information within 72 hours of receipt of request and allow at least 48 hours for provider to submit.

ii. CVS Caremark will make a determination within 48 hours from receipt of completed information or the end of the period afforded to provide the specified information.

4. The PA Department will make a determination and give notice to the provider and Member regarding the determination for non-formulary drugs within the following timeframes:

a. Urgent non-formulary requests will be completed within one (1) business day or 24 hours from the receipt of request, whichever is shorter.

b. Non-urgent non-formulary requests will be completed within one (1) business day or 72 hours from receipt of request, whichever is shorter.

Notice of Adverse Action or Denial

a. The PA Team will notify the requesting provider and Member of an adverse determination. This standard notice must include:

i. The type of review performed;

ii. The reason(s) for the Adverse Determination;

iii. Alternate length of treatment or the alternate treatment settings, if any, that CVS Caremark would approve or would have approved;

iv. A reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based;

v. Instructions for the provider on behalf of the member to seek reconsideration of the adverse determination, including contact name, address and telephone number of the person responsible for making the Adverse Determination;

vi. Description of the appeals process including, but not limited to time limits, contact name, addresses, telephone and fax number for filing an appeal.

vii. A statement indicating that the member or the member's authorized representative has the right to request an expedited external review without first exhausting the internal appeals process if the member's adverse determination involves the treatment of cancer or a medical condition where the time frame for completion of an expedited internal appeal would seriously jeopardize the life or health of the member or would jeopardize the member's ability to regain maximum function.

SUMMARY

The written policies discussed herein, pertaining to the determination of which MH/SUD and M/S drugs require step therapy, the development of coverage criteria, and the process of conducting prior authorization of MH/SUD and M/S drugs subject to a step therapy requirement, all apply equally to MH/SUD and M/S drugs and demonstrate use of the factors, the evidentiary standards and sources identified in Step 2, and the process for development of the same. No separate policies or procedures exist with respect to step therapy for MH/SUD drugs as compared to M/S drugs. Accordingly, as written, the processes, strategies, evidentiary standards and other factors used to design and apply step therapy with respect to MH/SUD benefits are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other

factors used to design and apply step therapy with respect to M/S benefits in the prescription drug benefit classification.

Step 5: Demonstration of Comparability and Stringency, In Operation

Step 5 addresses how, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to M/S benefits. This includes an explanation of any methodology and underlying data used to demonstrate the application of the NQTL.

This section demonstrates that, in operation, the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards and other factors used in designing and applying step therapy to M/S drugs.

As discussed in Step 4 above, the application of step therapy within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S prescription drugs. The operational procedures for prior authorization of M/S and MH/SUD drugs that require step therapy are identical across both benefit categories. The operation of the step therapy process demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Additionally, an in-operation analysis is conducted by reviewing the following:

- Prior Authorization/Step Therapy Approval and Denial Rates
- Coverage Determination Case Audits

APPROVAL/DENIAL RATES – STEP THERAPY

Evaluation of denial rates for M/S and MH/SUD step therapy requests is one measure that can evaluate whether step therapy is applied comparably, and not more stringently to MH/SUD drugs compared to M/S drugs. The data below reflects step therapy decisions for MH/SUD and M/S drugs on the **Aetna Standard Opt Out Formulary – Aetna for 2025**. The data reflects the total number of decisions and the total number of decisions that were approved and denied.

Approval/Denial Rates – Step Therapy Exceptions			
VIRGINIA - Aetna Standard Opt Out Formulary – 2025			
Drug Type	MED/SURG	MH	SUD
Total Requests	2	-	-
Total Approvals	2	-	-
Total Denials	-	-	-
Approval Percent	100.0%	0.0%	0.0%
Denial Percent	0.0%	0.0%	0.0%
Average TAT in Days	-	-	-

There were no step therapy requests for MH or SUD drugs to compare to M/S drugs during the reporting period.

COVERAGE DETERMINATION CASE AUDITS

Additionally, to evaluate whether, in the prescription drug benefit classification, the processes for applying utilization management to MH/SUD drugs are comparable to, and applied no more stringently than the processes used in applying limitations to M/S drugs, Aetna requests that its delegate Caremark audit a random sample of denied prior authorization, step therapy, and quantity limits exception requests including both MH/SUD and M/S drugs. For each question described in the methodology below, the auditor reviewed the clinical reviewer's work to determine whether the initial review correctly followed the plan's utilization review program expectations regarding specific tasks related to the coverage request and review process. The methodology and results of that analysis are described below.

Methodology

- A random sample of denied coverage determination cases were selected for the relevant formularies. Since there were no requests specific to the Standard Opt Out, cases from the Aetna Advanced Control and Exchange formularies were utilized for the audit to evaluate the application of the NQTL, overall.
- Requests in the sample originated from prescribers who used either electronic prior authorization tools (EPA) or submitted paper, fax, or telephonic requests.
- The following cases were excluded from the universe of eligible cases:
    - Cases involving drugs that may be used to treat either MH/SUD or M/S conditions were excluded from the analysis due to the inability to consistently identify the diagnosis as this is not a required field in the claims transmission process for PA requests. The case data set included drugs which are specifically indicated to treat either a MH/SUD or Med Surg condition.
- After selection of a random sample of denied coverage determinations, the following questions were evaluated as part of the case audit to assess review behavior, specifically

with respect to adherence to standard operating procedures that do not consider the classification of the prescription drug:

- Were correct criteria or guidelines used?
- Were the criteria questions answered correctly?
- Was the case decisioned by the appropriate final reviewer?
- Was the correct decision on the case made based on the applicable clinical criteria?
- Was the decision turn-around time in compliance with policy requirements?

Each case was audited by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.

Results

The results of the audit were that the samples met parity requirements. Specifically, when MH/SUD cases were compared to M/S cases there was no difference in the operational steps that were followed or in the stringency of review required to make a decision. In each case, the criteria questions were answered accurately and completely, and the appropriate reviewer finalized the decision for the case. In all samples the correct decision was reached. The required urgent and standard turn-around times were consistently met for both MH and M/S drugs. In sum, there were no differences in the processes for application of the UM requirements between MH/SUD and M/S drugs, confirming that, in operation, the application of the NQTLs to MH/SUD drugs was comparable and no more stringent than the application of NQTLs to M/S drugs.

CONCLUSION

In sum, based upon review of the data and information addressed herein, Aetna concludes that the processes, strategies, evidentiary standards or other factors used in designing and applying step therapy with respect to MH/SUD drugs are comparable to and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying step therapy with respect to M/S drugs in the prescription drug benefit classification.

Step 6: Findings and Conclusions

Step 6 addresses the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH/SUD and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation. This section includes: (a) any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of 45 CFR § 146.136(c)(4), and a reasoned and detailed discussion of these findings and conclusions; (b) if applicable, citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described herein not otherwise discussed in the comparative analysis; (c) the date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and (d) to the extent applicable, if the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

As demonstrated in **Step 1**, Aetna delegates the administration of prescription drug benefits to its PBM, Caremark, including utilization management for prescription drugs. In the prescription drug benefit classification, utilization management refers to the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and/or medications under the provisions of the applicable health benefits plan. Step therapy refers to criteria that define the circumstances under which a drug requiring prerequisite therapy will be systematically paid under a prescription benefit or reviewed through the prior authorization process.

Step 2 identified the factors that are used to determine the M/S and MH/SUD drugs that are subject to step therapy requirements, and the development of coverage criteria for drugs that require step therapy, as well as the evidentiary standards and sources for those factors. **Step 3** explained how these factors are used in the design and application of step therapy. As noted in Step 3, there are no differences in how those standards are applied to M/S and MH/SUD drugs. **Step 4** then explained how the factors are applied, in writing, to M/S and MH/SUD drugs that are subject to step therapy and concluded that there are no written differences in that application that results in MH/SUD drugs being treated more stringently than, or incomparably to, M/S drugs. Finally, **Step 5** demonstrated that, in operation, M/S and MH/SUD drugs are subject to step therapy in a comparable manner, and the MH/SUD drugs to which step therapy applies are treated substantively and administratively in a comparable and no more stringent manner than for M/S drugs. Specifically, Aetna did not identify any findings or conclusions indicating that Aetna is not, or might not be, in compliance with the requirements of 45 CFR § 146.136(c)(4). The comparative analysis conducted above demonstrates that step therapy is designed and applied in a comparable manner to MH/SUD and M/S drugs.

As demonstrated in **Step 4**, as written, the same written materials, policies and procedures apply to both MH/SUD and M/S drugs, with respect to determining the M/S and MH/SUD drugs that are subject to step therapy, the development of coverage criteria for drugs that require step therapy, and the process of conducting prior authorization for M/S and MH/SUD drugs subject to step therapy. An as-written comparative analysis was conducted by reviewing utilization management policies and procedures, including those that document the factors, sources and evidentiary standards that are used to design and apply step therapy. That analysis shows that no separate policies or procedures exist with respect to step therapy for MH/SUD drugs as compared to M/S drugs. The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to M/S drugs. The policies show that these experts evaluate and consider the factors for applying step therapy in the same manner, regardless of whether a drug is used to treat a MH/SUD or M/S condition or disease. The groups discussed in Step 3 that conduct the relevant evaluations include personnel with MH/SUD expertise. Caremark conducts a comparative and stringency evaluation of NQTLs (prior authorization, step therapy and quantity limits) for MH/SUD and M/S drugs to determine whether the design of the NQTL meets parity when a new drug is deemed appropriate for the application of an NQTL, as part of the annual review process and more frequently as needed. Further, consistent with CVS Caremark® Policy and Procedure – DOC-049152, Prior Authorization Process (Virginia), all review requests are processed accurately and in a timely manner in compliance with state and federal regulations, in a comparable manner for medications used to treat MH/SUD or M/S conditions or diseases. This information and review demonstrate that, as written, step therapy is designed and applied comparably to drugs used to treat M/S and MH/SUD conditions and is not more stringently applied to drugs used to treat MH/SUD conditions than M/S conditions.

As demonstrated in **Step 5**, in operation, step therapy is applied in a comparable manner for both M/S and MH/SUD drugs. The application of step therapy within the prescription benefit classification operates under consistent processes and criteria for both MH/SUD and M/S drugs. Further, the operational procedures for conducting prior authorization for drugs subject to step therapy are identical across both benefit categories. The operation of the prior authorization process for step therapy demonstrates parity, as it is comparably designed and applied with no greater stringency to MH/SUD drugs than to M/S drugs. There are no additional procedural burdens or delays imposed on MH/SUD prescriptions that would result in disparate treatment under MHPAEA. Specifically, as set forth in Step 5, a review was conducted of step therapy approval and denial rates. There were no step therapy requests for MH or SUD drugs to compare to M/S drugs Additionally, to demonstrate in-operation parity with respect to reviewer activities evaluating utilization management coverage determinations, a random sample of denied cases was audited in accordance with the methodology detailed at Step 5. The review of the cases demonstrated that the process for reviews was consistent across all utilization management requests for MH/SUD and M/S cases, and that the MH/SUD cases were properly conducted.

From this information, Aetna concludes that both in writing and in operation, the processes, strategies, evidentiary standards, and other factors used to design and apply step therapy to MH/SUD drugs are comparable to, and are applied no more stringently, than the processes, strategies, evidentiary standards, and other factors used in designing and applying step therapy to M/S drugs.

Analysis completed:	September 21, 2026
Relevant persons who participated in the performance and documentation of the comparative analysis:	• Senior Manager, Project Management, Health Plans Pharmacy Business Analytics (Aetna) • Senior Clinical Pharmacist, Aetna Pharmacy Health Plan (Aetna) • CVS Caremark® (Delegate)

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Appendix A. Aetna Provider Manual Sections Pertaining to Utilization Management

This appendix includes sections relevant to the NQTL Comparative Analysis from Aetna's **Provider Manual**, which is available at aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/office_manual_hcp.pdf

Utilization management

Overview

Our model includes utilization management, case management, disease management, and specialty programs such as behavioral health. Our role is to help coordinate health care and to encourage members to be informed participants in health care decision-making.

Our activities for hospitalized members include:

- Focused discharge planning to help with the member's transition to the next level of care
- Targeted, concurrent review of the member's hospital course of treatment to evaluate the appropriate level of coverage for medical services

***Note**: For these purposes, coverage means either of the following:*

- *The determination of whether or not the particular service or treatment is a covered benefit pursuant to the terms of the particular member's benefits plan*
- *The determination of where a provider is required to comply with our utilization management programs, whether or not the particular service or treatment is payable under the terms of the provider agreement*

Utilization management and standards

We use utilization review to promote adherence to accepted medical treatment standards. Additionally, utilization review encourages participating physicians to minimize unnecessary medical costs consistent with sound medical judgment. We require participating providers to adhere to the following requirements:

- Participate, as requested, and collaborate with Aetna utilization review, care management and quality improvement programs and with all other related programs (as modified from time to time) and decisions with respect to all members.
- Regularly interact and cooperate with Aetna clinicians.
- Adhere to Aetna participation criteria and processes, including site visits and medical chart reviews, and submit to these processes when applicable.
- Cooperate to help us review and transition members hospitalized in a nonparticipating facility to a participating facility.
- Obtain advance authorization from Aetna prior to any nonemergency admission. In addition, when a member requires an emergency hospital admission, notify us, according to our rules, policies and procedures in effect.
- To the extent medically appropriate and required by the plan's terms, refer or admit members only to participating providers for covered services. Provide complete information on treatment procedures and diagnostic tests performed prior to the referral or admission.
- Abide by CMS's Medicare Outpatient Observation Notice (MOON) requirement provided to members and related to observation services.

You may have an Aetna patient who requires services under an Aetna specialty program. If so, we expect you to work with us to transfer the member's care to a specialty program provider.

Utilization review policies

Summaries of utilization review policies, including prior authorization, concurrent review, discharge planning and retrospective review are located on our public website to determine:

- Whether or not the particular service or treatment is a covered benefit under the member's benefits plan
- When a provider is required to comply with Aetna utilization management programs
- Whether or not the particular service or treatment is payable under the terms of the provider agreement

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How we determine coverage

Coverage determinations staff and guidelines

Aetna medical directors make all coverage denial decisions that involve clinical issues. Only Aetna medical directors and licensed dentists, oral and maxillofacial surgeons, psychiatrists, psychologists, board-certified behavior analysts-doctoral (BCBA-D) and pharmacists make denial decisions for reasons related to medical necessity. (Licensed dentists, pharmacists and psychologists review coverage requests as permitted by state regulations.) Where state law mandates, utilization review coverage denials are made, as applicable, by a physician or pharmacist licensed to practice in that state.

Our Patient Management staff use evidence-based clinical guidelines from nationally recognized authorities to guide utilization management decisions involving prior authorization, inpatient review, discharge planning and retrospective review. Staff use the following criteria as guides in making coverage determinations, which are based on information about the specific member's clinical condition:

- State-mandated use of particular criteria and guidelines
- **MCG Care Guidelines** (Seattle, WA: MCG Health, LLC)
- Level of Care for Alcohol and Drug Treatment Referral (LOCADTR)
- This is used in place of The American Society of Addiction Medicine (ASAM) for chemical dependency treatment provided in New York
- Aetna Clinical Policy Bulletins (CPBs), Pharmacy Clinical Criteria, and Medicare Part B UM Drug Coverage Criteria as appropriate
- **Centers for Medicare & Medicaid Services** (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and the Medicare Benefit Policy Manual
- National Comprehensive Cancer Network (NCCN) Guidelines
- Level of Care Utilization System (LOCUS) and Child and Adolescent Level of Care/Service Intensity Utilization System and Child and Adolescent Service Intensity Instrument (CALOCUS-CASII)
- Aetna's Applied Behavior Analysis (ABA) Medical Necessity Guide
- Aetna Custodial Care Guidelines
- The American Society of Addiction Medicine (ASAM) Criteria: Treatment for Addictive, Substance-Related, and Co-Occurring Conditions, Third Edition. This content is copyrighted. Contact the American Society of Addiction Medicine at **ASAMcriteria@asam.org** for information on how to purchase it.

Participating physicians may ask for a hard copy of the criteria that were used to make a determination by contacting our Provider Contact Center at **1-888-632-3862 (TTY: 711)**. Participating physicians also have access to the criteria at point of care through the provider portal and Aetna website.

Medical necessityand medically necessary

Under most plans, the term "medically necessary" and "medical necessity" refer to health care services that a physician provides to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms.

These services adhere to the following generally accepted standards of medical practice:

- They are clinically appropriate in terms of type, frequency, extent, site, place of service and duration, and considered effective for your illness, injury or disease.
- They are not primarily for the convenience of the patient, physician or other health care provider.
- They are not more costly than an alternative or sequence of services that are at least as likely to produce equivalent results.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature. These standards are generally recognized by the relevant medical community or otherwise consistentwith the standards above.

Note: *Each state may have its own definition of "medically necessary" or "medical necessity." You may be required to adhere to those standards imposed by the state's definition based on the state you practice in.*

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Peer-to peer review

At times, we base decisions on the appropriateness of care and service. We review coverage requests to determine if the requested service is a covered benefit under the terms of the member's plan and is being delivered consistent with established guidelines.

Aetna offers providers an opportunity to present additional information and discuss their cases with a peer-to-peer reviewer as part of the utilization review coverage determination process. The timing of the review incorporates state, federal, CMS and NCQA requirements. If we deny a request for coverage, the member (representative, which may include an attorney or a physician acting on the member's behalf) may appeal this decision through the **Complaint and appeal process**. Depending on the specific circumstances and member's benefit plan, the appeal may be made, as applicable to:

- A government agency
- The plan sponsor
- An external utilization review organization that uses independent physician reviewers

We do not reward physicians or other individuals who conduct utilization reviews for issuing denials of coverage or for creating barriers to care or service. Financial incentives for utilization management decision-makers do not encourage denials of coverage or service. Rather, we encourage the delivery of appropriate health care services. In addition, we train utilization review staff to focus on the risks of underutilization and overutilization of services. We do not encourage utilization-related decisions that result in underutilization.

How to contact us about utilization management issues

You may call us during and after business hours via toll-free phone numbers.

Health care providers may contact us during normal business hours (8 AM to 5 PM, Monday through Friday) by calling the toll-free prior authorization number on the member ID card. When only a Member Services number is on the card, you'll be directed to the Prior Authorization Unit through a phone prompt or a Member Services representative.

Our staff, including medical directors, are also available after hours, on weekends and on company holidays to assist with provider and member inquiries regarding utilization management issues via the toll-free numbers.

Note: *For all continental U.S. time zones; hours of operation may differ based on state regulations. Texas: 6 AM to 6 PM CT, Monday through Friday, and 9 AM to noon CT on weekends and legal holidays. (For all other times, phone recording systems are used.)*

Prior authorization

Prior authorization, also referred to as precertification, is the process of collecting information before inpatient admissions and certain ambulatory procedures and services. Prior authorization applies to:

- Procedures and services on the Aetna Participating Provider Prior Authorization List
- Procedures and services on the Aetna Behavioral Health Prior Authorization List
- Procedures and services that require prior authorization under the terms of a member's plan
- Any organization determination requested by a Medicare Advantage member, appointed representative or physician for a coverage decision

The Centers for Medicaid and Medicare Services (CMS) defines an appointed representative ("representative") as an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. Unless otherwise stated, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination, filing a grievance, or in dealing with any of the levels of the grievance or appeals process, subject to the applicable rules described in 42 CFR 422 Subpart M. To meet the CMS definition of appointed representative, the member and the member's appointed representative must both sign and date a representative form.

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Note: *The term "prior authorization" (used here and throughout the office manual) refers to the utilization review process used to determine if a requested service, procedure, prescription drug or medical device meets our clinical criteria for coverage. It does not mean prior authorization as defined by Texas law. Texas law defines prior authorization as a reliable representation of payment of care or services to fully insured health maintenance organization (HMO) and preferred provider organization (PPO) members.*

Prior authorization process

Prior authorization is the process of determining the eligibility for coverage of the proposed level of care and place of service. The process includes:

- Confirmation of member eligibility
- Assessment of medical necessity
- Communicating a coverage decision to the treating practitioner and/or member before the procedure, service or supply
- Identifying members for pre-service discharge planning
- Identifying and registering members for covered Aetna specialty programs, such as case management and disease management, behavioral health, the National Medical Excellence Program and the Aetna Women's Health Program

If we need to review the applicable medical records, we may provide you with, and you need to agree to accept, a prior authorization reference pending or tracking number. The reference number is not an approval. You will be notified once a coverage decision is made.

Use our online tools to help you determine if precertification is required for a particular procedure. Then, submit precertification requests for those services.

- Precertification Code Search tool — allows you to enter up to five CPT codes at a time to determine whether a medical prior authorization is required for your patient.
- Online prior authorization transaction — allows you to add a prior authorization request for those services that require it and inquire to see if a prior authorization has been approved.

You can submit a prior authorization by electronic data interchange (EDI), through our **provider portal** or by phone, using the number on the member's ID card. Based on historical experience, we may sometimes allow particular providers to follow a streamlined prior authorization process for certain services.

You may also submit unsolicited medical records using one of our participating vendors through an electronic attachments transaction (X12N 275). View our list of **participating prior authorization vendors thatacceptunsolicitedattachments for prior authorization**.

Visit our website to learn more about **prior authorization** and check out our **prior authorization lists**.

Note: Prior authorization may be the member's responsibility in certain plan types that offer out-of-network benefits. Per Medicare laws, rules and regulations, there is no penalty to Medicare Advantage plan members if they do not get prior authorization.

Admissions protocol

The admitting physician must electronically submit or contact us for preadmission authorization. Our prior authorization staff can take authorization requests directly from hospital admissions personnel. Members can begin the prior authorization process with Aetna independently. However, if the preadmission information isn't complete, we contact the admitting physician for clarification. If the admission is approved for surgical cases, we assign a recommended length of stay (RLOS).

This determines when a review will start. For other cases, we give specific guidelines with the admission prior authorization. The RLOS determination is primarily based on MCG Care Guidelines.

Notice for emergency and other inpatient admissions

We need to be notified of all inpatient admissions,

including those through the emergency department, within two business days of the admission. If a patient is unable to provide coverage information, you must contact us as soon as you become aware of their Aetna coverage. You must also explain any extenuating situation at the time of your notification. You may contact us by phone (call the number on the patient's member ID card) or through electronic data interchange (EDI) through our **provider portal**. Certain admission exclusions may apply. The timely Notification Policy and all Aetna payment policies can be found on **Availity**; or you can call the Provider Contact Center. To sign up for Availity, follow instructions on **Aetna.com**.

Emergencies

State regulations and contractual provisions regarding emergency admissions may, in some cases, overrule the procedures described in this manual.

Medical emergencies

If an Aetna member requires emergency care, they're covered 24 hours a day, 7 days a week, anywhere in the world. In the event of a medical emergency, regardless of whether they are in or out of an Aetna service area, we advise our members to follow the guidelines below when accessing emergency care:

- Call 911 or go to the nearest emergency facility. If a delay would not be detrimental to the patient's health, call the primary care physician.
- After assessing and stabilizing the patient's condition, the emergency facility should contact the primary care physician so they can assist the treating physician by supplying information about the patient's medical history.
- If the member is admitted to an inpatient facility, the patient, a family member or friend acting on behalf of the patient should notify the primary care physician or Aetna as soon as possible.
- All follow-up care should be coordinated by the primary care physician, where applicable (medical only).

An "emergency medical condition" involves acute symptoms that are severe enough that someone with an average knowledge of health could expect that the absence of medical attention would result in serious harm. For pregnant women, the health of both the woman and her unborn child must be taken into consideration. State mandates may apply. Depending on the benefits plan, members traveling outside their service area or students who are away at school are covered for emergency and urgently needed care.

Claims submitted to us by the provider that supplied care must appear to meet the standards for emergency or urgent care. Otherwise, we may need to review the records from the emergency visit. In this situation we will send a request to the treating facility for the records of the visit and notify the member of the request. If the member wishes, they may provide us with additional information regarding the circumstances of the visit.

Aetna Behavioral Health

Aetna Behavioral Health refers to an internal business unit of Aetna. On **Aetna.com**, you'll find:

- Archived issues of our **Office Links Updates** newsletter with information for participating behavioral health professionals
- **AetnaBehavioralHealthPrograms** overview
- **Utilization Management** and how we determine coverage

Our guiding principles

Our behavioral health programs support our belief in the following:

- Enhancing our members' — your patients' — clinical experiences
- Adhering to the importance of the mind-body principle and connection
- Providing a treatment approach that is evidence-based, goal-directed, and consistent with accepted standards of care, all Aetna Clinical Policy Bulletins, and Aetna clinical practice guidelines
- Providing treatment that is medically necessary
- Educating members about the risks and benefits of available treatment options

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- Developing a strong relationship with you, informing you about resources, and concentrating on continuity of care among all, for the benefit of you and your patients
- Integrating behavioral health care across our product spectrum

Access to care

Members may access behavioral health care in three ways:

- Through direct access to the behavioral health provider
- Through a recommendation from the primary care physician or other treatment provider
- Through a referral from an employee assistance or student assistance program provider

Clinical management and delivery

How we determine coverage

Our medical directors make all coverage decisions that involve clinical issues. Only licensed medical directors, psychiatrists/psychologists and pharmacists make denial decisions for reasons related to medical necessity. (Licensed pharmacists and psychologists review coverage requests, as permitted by state regulations.)

Patient Management staff use evidenced-based clinical guidelines from nationally recognized authorities to guide utilization management decisions involving prior authorization, inpatient review, discharge planning and retrospective review. Staff use the following criteria as guides in making coverage determinations, which are based on information about the specific member's clinical condition.

Where state law mandates, utilization review coverage denials are made, as applicable, by a physician or a pharmacist who is licensed to practice in that state.

To ensure Aetna members receive the highest quality of care, a comprehensive diagnostic evaluation prior to the initiation of treatment is expected. Diagnoses submitted on claims must be current and consistent with the most recent Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria. Collecting complete and accurate clinical data is critical to successfully completing the authorization process. Treatment approach is expected to be evidence-based, goal directed, and consistent with accepted standards of care, Aetna Clinical Policy Bulletins and Aetna clinical practice guidelines. It is also expected that treatment provided is **medically necessary**.

In addition to reviewing clinical information to determine coverage, our utilization management clinician will discuss treatment alternatives, the appropriate level of care and explore discharge planning opportunities. If Aetna case management is involved, we will request that the member's family, physician(s), and other health care professionals be involved in the treatment plan and activities. We recommend that you discuss the available benefits for outpatient care with your patient, so that treatment can be planned accordingly.

Note: *For these purposes, "coverage" means either the determination of (i) whether or not the particular service or treatment is a covered benefit under the terms of the particular member's benefits plan, or (ii) where a physician or health care professional is required to comply with the Aetna patient management programs, whether or not the particular service or treatment is payable under the terms of the provider agreement.*

Utilization management coverage determinations

We use evidence-based clinical guidelines from nationally recognized authorities to make utilization management (UM) decisions. We base decisions on the appropriateness of care and service. We review coverage requests to determine if the requested service is a covered benefit under the terms of the member's plan and is being delivered consistently with established guidelines.

Aetna offers providers an opportunity to present additional information and discuss their cases with a peer-to-peer reviewer as part of the utilization review coverage determination process. The timing of the review incorporates state, federal, Centers for Medicare & Medicaid Services (CMS) and National

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Committee for Quality Assurance (NCQA) requirements.

If we deny a request for coverage, the member (or a physician acting on the member's behalf) may appeal this decision through the complaint and appeal process. Depending on the specific circumstances, the appeal may be made to a government agency, the plan sponsor, or an external utilization review organization that uses independent physician reviewers, as applicable.

We don't reward physicians or other individuals who conduct utilization reviews in order to issue denials of coverage or create barriers to care or service.
Financial incentives for utilization management decision makers don't encourage denials of coverage or service. Rather, we encourage the delivery of appropriate health care services. In addition, we train utilization review staff to focus on the risks of underutilization and overutilization of services. We don't encourage utilization-related decisions that result in underutilization.

Level of Care Utilization System

The **Level of Care Utilization System** for Psychiatric and Addiction Services, or LOCUS, is a nationally recognized level of care tool used to help determine the resource intensity needs of individuals who receive adult mental health services.

It is used for patients 18 years and older who are in need of placement in specialized psychiatric or mental health facilities or units. This person-centered approach aims to find the best fit between individual needs and behavioral health services. For more information about LOCUS, visit the American Association of Community Psychiatry (AACP) website at **CommunityPsychiatry.org**.

The Child and Adolescent Level of Care/Service Intensity Utilization System and Child and Adolescent Service Intensity Instrument, or CALOCUS-CASII, are nationally recognized tools used to determine the appropriate level of care placement for a child or adolescent. These tools are used for children and adolescents from 6 to 17 years of age. For more information about these tools, visit the American Academy of Child and Adolescent Psychiatry (AACAP) website at **AACAP.org**.

Note: *The LOCUS and CALOCUS/CASII are instruments that an Aetna clinician uses to aid in the decision-making process. They help determine the level of care appropriate for effective treatment for a mental health patient. "Aetna clinician" may mean a Licensed Behavioral Health Clinician or RN, an independent physician reviewer working on our behalf or an Aetna medical director. LOCUS and CALOCUS/CASII guidelines don't constitute medical advice. Treating providers are solely responsible for medical advice and treatment of members.*

The ASAM Criteria: Treatment Criteria for Addictive Substance-related and Co-occurring Conditions

This is a nationally recognized criteria set that helps determine appropriate levels and types of care for patients in need of evaluation and treatment for chemical dependency and substance use conditions and diagnoses. The third edition is compliant with the DSM-5 and also applies for patients who are in need of placement in specialized chemical dependency detoxification or rehabilitation facilities or units.

State-specific guidelines

Level of Care for Alcohol and Drug Treatment Referral (LOCADTR) is used for chemical dependency treatment that takes place in New York.

Some states have specific requirements or laws in place for practitioners and facilities. For more information on state-specific requirements, see our **Provider Manual State Supplement**.

The Aetna Applied Behavior Analysis (ABA) Medical Necessity Guide

The ABA Medical Necessity Guide is a clinical behavioral health patient-management instrument used to guide and track treatment decisions for our members in need of ABA. For practitioners treating autism spectrum disorders using ABA, either national certification is needed from the Behavior Analyst Certification Board (BACB), or the practitioner must be licensed as a behavior analyst in the state in which they practice.

Aetna Clinical Policy Bulletins (CPBs)

These are based on evidence in peer-reviewed, published medical literature; technology assessments and structured evidence reviews;

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evidence-based consensus statements; expert opinions of health care providers; and evidence-based guidelines from nationally recognized professional health care organizations and government public health agencies. CPBs are detailed technical documents that explain how we make coverage decisions for members under our health benefits plans. They spell out what medical, dental, pharmacy and behavioral health technologies and services may, or may not, be covered.

Both new and revised CPB drafts undergo a comprehensive review process that includes review by our Clinical Policy Council. Our chief medical officer (or designee) approves CPBs. The Aetna Clinical Policy Council evaluates the safety, effectiveness, and appropriateness of medical technologies (that is, drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided) that are covered under our medical plans, or that may be eligible for coverage under our medical plans.

In making this determination, the Clinical Policy Council reviews and evaluates evidence in the peer-reviewed, published medical literature; information from the U.S. Food and Drug Administration and other federal public health agencies; evidence-based guidelines from national medical professional organizations; and evidence-based evaluations by consensus panels and technology evaluation bodies.

The Aetna Custodial Care Guidelines

When care is deemed to fall under custodial care, the care is no longer eligible for coverage. Based on the information provided the Member has reached the maximum achievable level of mental function with the current treatment at the current level of care; and/or the services are given mainly to maintain, rather than improve, a level of mental function, and/or provide a surrounding free from environmental conditions that can worsen the person's physical or mental state.

You can learn more about these guidelines on the utilization management page on Aetna.com.

More information

The criteria noted above are only guidelines. Their use doesn't preclude the requirement that trained, licensed, credentialed and experienced behavioral health professionals must exercise their independent professional judgment when providing behavioral health care services to our members.

Referrals for evaluation and/or treatment of chemical dependency and mental health issues will be reviewed by a psychiatrist or licensed clinician to determine the appropriate level of care.

If you need hard copies of any of Aetna Behavioral Health UM criteria or CPBs, call us at:

- Provider Service Center: **1-800-624-0756 (TTY: 711)**
- HMO and Aetna Medicare Advantage plans: **1-800-624-0756 (TTY: 711)**
- All other plans: **1-888-MDAetna (TTY: 711)** or **1-888-632-3862 (TTY: 711)**

For current information on our medical necessity criteria or Clinical Policy Bulletins, visit **Aetna.com/health care-professionals/clinical-policy-bulletins.html** for our Clinical Policy Bulletins page.

Prior authorization

Prior authorization is the process of determining the eligibility for coverage of the proposed level of care and place of service. Prior authorization occurs before inpatient admissions and select ambulatory procedures and services. Use our online tools to help you determine if prior authorization is required for a particular procedure. You can submit a prior authorization request the following ways:

- Through **Availity.com** (our provider portal)
- Through one of our vendors — go to **Aetna.com/health-care-professionals/claims-payment-reimbursement/electronic-transaction-vendors.html** to see our list
- By calling our Provider Service Center at **1-800-624-0756 (TTY: 711)**
- By calling the toll-free behavioral health/prior authorization number on the member's ID card

To request prior authorization, use our provider portal at **Availity.com** or any other website that allows you to send prior authorization requests electronically.

Visit our website for a general list of services that

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require prior authorization and concurrent review, and to learn more about **prior authorization**.

Note: *The term prior authorization (used here and throughout the office manual) refers to the utilization review process used to determine if a requested service, procedure, prescription drug or medical device meets our clinical criteria for coverage.*
It does not mean prior authorization as defined by Texas law. Texas law defines prior authorization as a reliable representation of payment of care or services to fully insured health maintenance organization (HMO) and preferred provider organization (PPO) members.

Outpatient care

It's important to note that outpatient care that isn't consistent with evidence-based, goal-directed practices, Aetna Clinical Policy Bulletins and Aetna clinical practice guidelines may be subject to quality-of-care and utilization reviews.

Also note that outpatient care inconsistent with such a treatment approach may be subject to prior authorization.

Assessing for comorbidity

It's expected that facility diagnostic evaluations assess for either comorbid chemical dependency or comorbid psychiatric conditions that could be impacting current presentation.

Stepping down care

Stepping down to a less restrictive level of care within the same facility (for example, a step down from inpatient detoxification to inpatient rehabilitation), even within the same unit of the same facility, requires prior authorization.

Out-of-network referrals

A member may sometimes seek treatment outside of our network (for example, a nonparticipating referral for routine outpatient behavioral health services). This is a written or oral request that we review. Reasons that a nonparticipating referral may be approved include:

- When a specific health care professional preferred by the member isn't available in network (and the member's plan provides coverage for out-of-network services)
- When the member is continuing, or returning to, treatment with a nonparticipating health care professional, in certain circumstances
- When the primary care practitioner identifies a local or known nonparticipating health care professional with expertise in the treatment of the member's condition (and the member's plan provides coverage for out-of-network services)

Prior authorization for ABA

Applied behavior analysis (ABA) services require prior authorization. To get ABA services precertified, call the number on the member's Aetna ID card and speak to a Member Services representative.

See our **medical necessity guidelines for ABA**.

We've used the American Medical Association Category I CPT codes (97151–97158) for Adaptive Behavior Treatment as of January 1, 2019, and Category III CPT codes (0362T and 0373T).

Exceptions

The prior authorization process applies to all Aetna plans with the exception of behavioral health benefits that we administer but do not control and self-funded plans with plan sponsors that have expressly purchased specific prior authorization requirements.

*FOR NALOXONE SOURCE: Wheeler E, Jones S, Gilbert MK, et al. Opioid overdose prevention programs providing naloxone to laypersons — United States, 2014. Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR). June 19, 2015. Available at: **CDC.gov/mmwr/preview/mmwrhtml/mm6423a2.htm**. Accessed January 8, 2025

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Appendix B. Aetna Provider Manual Sections Pertaining to Network Adequacy and Credentialing

This appendix includes sections relevant to the NQTL Comparative Analysis from Aetna's **Provider Manual**, which is available at aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/office_manual_hcp.pdf

Credentialing and recredentialing

You must be credentialed in order to initially participate in our network. Thereafter, to continue to participate, you must be recredentialed every three years, unless otherwise required by state regulations, federal regulations or accrediting agency standards.

All credentialing and recredentialing activities are performed by a National Committee for Quality Assurance (NCQA)-certified credentialing verification organization. When using the Council for Affordable Quality Healthcare (CAQH), or any other approved credentialing application vendor, remember that you must designate Aetna as an authorized health plan to access your credentialing application.

Facilities

During the credentialing process for facilities, we review to determine if the facility is in good standing with both state and federal regulatory bodies and if it is accredited by an Aetna-recognized accrediting entity. If it is not accredited by an Aetna-recognized accrediting entity, we check to see if a Centers for Medicare & Medicaid Services (CMS) survey, a state survey or other on-site quality assessment was conducted.

Health care professionals

During the credentialing process for health care professionals, we review the provider's qualifications, practice and performance history.

- In most states we use CAQH ProView to get your credentialing application, unless otherwise required by state regulation.
- We use ARCCVS for physicians located in Arkansas.

Accessibility standards and participation criteria

Providers are required to comply with applicable regulatory requirements, as well as Aetna participation requirements, which are available in our **Network Participation Criteria Manual**.

Primary care physician/provider (PCP) responsibilities

PCPs will arrange the overall care and covered services for members according to their plan. This includes urgently needed or emergency services.

We have standards for member access to primary care services, which are listed in our participation criteria, along with other PCP criteria.

Specialty care provider responsibilities

We have standards for member access to specialty care services. Each specialty care provider is required to have appointments available, in person or via telehealth, within these time frames:

- Routine care: within 30 business days
- Urgent/emergent matter: immediately or referred to the emergency room, as appropriate

In addition, all participating specialty care providers must have a reliable 24/7 answering service or machine with a notification system for call-backs. A recorded message or answering service that refers members to emergency rooms is not acceptable. More stringent state requirements supersede these accessibility standards and are located in the **Provider Manual State Supplement**.

Aetna Behavioral Health Participation Criteria and accessibility standards

Providers are required to comply with Aetna participation requirements, which are available in our **Participation Criteria (PDF)**

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This appendix includes sections **relevant** to the NQTL Comparative Analysis from Aetna's **Provider and Facility Participation Criteria**, also referred to as the "Network Participation Criteria Manual" or "Participation Criteria PDF" in the provider manual. The full document is available at aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/network-participation-criteria-document.pdf

Ancillary core participation criteria and additional criteria

A. Applicability

1. If applicable, each provider must complete a facility credentialing questionnaire and will periodically supply all of the requested information to Aetna.

D. Access and availability of services

If applicable, each provider's office/business must:

1. Offer a reliable mechanism for members and other health care professionals to be reached 24/7.
2. Ensure that they render coverage for members 24/7 or else arrange to have another Aetna participating provider available.
3. Be geographically accessible for outpatient services and consistent with local community patterns of care for the geographic area. This helps ensure that a member doesn't have to travel more than 30 minutes from the member's regular provider's office/business to get to the covering provider's services.

G. Insurance

Provider will maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by providers in your state or region.

Provider must ensure that their insurance coverage extends to all states where care is being rendered. If Provider is providing services across multiple states, the limit obtained should be the greater of any applicable state specific requirement.

The insurance coverage will cover provider and its/their agents and employees.

Provider will give Aetna proof of insurance coverage upon request.

Provider must give at least thirty (30) days' advance notice of any cancellation or material changes to these policies, and must post notice of malpractice insurance (existing, cancellation or exemption) in a prominent location in the office.

Facility core participation and additional criteria

Facility core participation criteria

A. Applicability

1. If applicable, each provider must complete a facility credentialing questionnaire and must periodically supply to Aetna all requested information.

C. Access and availability of services

Each facility's business must:

1. Offer inpatient hours 24/7.
2. Offer outpatient hours sufficient to meet the appointment access standards including evenings and weekends.

F. Insurance

Facility will maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by facilities in your state or region.

Facility must ensure that their insurance coverage extends to all states where care is being rendered. If Facility is providing services across multiple states, the limit obtained should be the greater of any applicable state specific requirement.

The insurance coverage will cover facility and its/their agents and employees.

Facility will give Aetna proof of insurance coverage upon request.

Facility must give at least thirty (30) days' advance notice of any cancellation or material changes to these policies, and must post notice of malpractice

insurance (existing, cancellation or exemption) in a prominent location in the office.

Physician, Nurse Practitioner, and Physician Assistant core participation criteria and additional criteria

Physician core criteria

These criteria, in addition to physician specific criteria, apply to each physician and the practice for the duration of the agreement. They will be enforced at the sole discretion of Aetna®. Any exceptions to the business criteria must be approved in advance by the Aetna.

A. Applicability

1. All physicians in a group practice must satisfy these participation criteria. If not, the group cannot participate.
2. As applicable, the physician applicant must be certified either by the American Board of Medical Specialties, the American Osteopathic Association or by an Aetna–recognized certifying board, unless the applicant meets an exception under Aetna policy. Any exceptions must be approved by the Aetna medical director or designee.
3. The physician must complete an application and periodically supply to Aetna all requested information.

D. Access and availability of services

Each physician's medical office must meet the following criteria:

1. Office must offer a reliable way for members and other health care professionals to be reached 24/7.
2. Office must have a process in place for responding to a member within 30 minutes after notification of an urgent call.
3. Office must ensure that they provide coverage for members 24/7, or else arrange for coverage with another Aetna participating physician.
   a. For outpatient services, a covering physician's office must be geographically accessible and consistent with local community patterns of care for the area to help ensure that a member does not have to travel more than 30 minutes from the member's regular physician's office to get help from the covering physician.

G. Insurance

Physician/physician group will maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by providers in your state or region.

Physician/physician group must ensure that their insurance coverage extends to any and all states where care is being rendered. If physician/physician group is providing services across multiple states, the limit obtained should be the greater of any applicable state specific requirement.

The insurance coverage will cover physician/physician group and its/their agents and employees.

Physician/physician group will give Aetna® proof of insurance coverage upon request.

Physician/physician group must give Aetna at least thirty (30) days' advance notice of any cancellation or material changes to these policies, and must post notice of malpractice insurance (existing, cancellation or exemption) in a prominent location in the office.

H. Professional competence and conduct criteria

1. Physician must not have an unsatisfactory professional liability claims history, including, but not limited to, lawsuits, arbitration, mediation, settlements or judgments. And must not have engaged in any unprofessional conduct, unacceptable business practices or any other act or omission and must not have a history of involuntary termination (or voluntary termination during or in anticipation of an investigation or dismissal) of employment or any other sort of engagement as a health care professional, of reduction or restriction of duties or privileges, or of a contract to provide health care services, which, in the view of the committee and/or applicable peer review committee, may raise concerns about possible future substandard professional performance, competence or conduct.

2. In the case of an encumbered license, the applicant demonstrates to the applicable peer review committee's satisfaction that encumbered license does not raise concern about possible future substandard professional performance, competence or conduct.

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I. References

1. Physician must supply professional references as requested by the applicable Aetna peer review committee.
2. The applicable Aetna peer review committee will have the right to act on any reference or information received from a physician's colleagues. Physician waives any and all rights to bring any legal action relating to such information or the collection or use thereof against Aetna; any affiliates or related companies or any director, officer, employee or agent thereof; or any person or entity providing a reference or information at the request of the applicable peer review committee.

Primary care provider additional criteria

If you are a provider serving as a primary care provider (PCP), the following additional criteria apply:

A. Definition

1. A primary care provider (PCP) must be a qualified health care professional (QHP) who specializes in family practice, general internal medicine, general pediatrics, or obstetrics/gynecology, or an equivalent/ similar area of practice and training, who has agreed to:
   a. provide primary care services, including, but not limited to, preventive, acute, and chronic condition care, using current evidence-based guidelines; and
   b. coordinate and manage covered services for members who have selected or been assigned to such provider if applicable under the plan.

B. Access and availability of services

1. Each primary care provider medical practice* must have a minimum of 20 regularly scheduled appointment hours over at least four days in a week to treat patients (whether members or other patients).
2. Each PCP must schedule appointments with members, at a minimum, within the following timeframes:
   a. Emergency/urgent care: must be seen immediately (or referred to emergency room, as appropriate)
   b. Symptomatic/non-urgent acute care: within seven business days
   c. Routine and preventive care: within thirty business days
   d. Follow-up care: as appropriate, if needed
3. All PCPs must have a reliable answering service or machine with notification system for callbacks available twenty-four hours per day, seven days per week (24/7). PCPs must have appropriate backup for absences. A recorded message or answering service that refers members to emergency rooms is not acceptable.
4. Where more stringent, state requirements supersede the above standards and are in the **Provider Manual State Supplement**.
   *If multiple locations are participating with Aetna, the requirements pertain to each location individually.

Specialist (physician) provider additional criteria

If you are a **specialist (physician)**, the following additional criteria apply:

A. Access and availability of services

1. Specialist physician will be available at least an average of eight hours a week for scheduling office appointments.
2. Accreditation as an office-based surgical facility is not sufficient for separate payment of facility fees or related surgical charges.
3. When applicable, specialist physician will provide readings of all imaging studies and notify the primary care physician or other referring physician according to the following standards:
   a. Urgent: within 30 minutes of completing the imaging study in cases deemed urgent by the primary care physician and/or referring physician
   b. Diagnostic tests: within one business day of completing the imaging study

Applied behavior analyst (ABA) services provider additional criteria

If you are an **ABA services physician,** the following additional criteria apply:

1. Services must be provided directly or supervised by individuals licensed by the state or certified by the Behavior Analyst Certification Board as board-certified behavior analysts (BCBAs). Supervised individuals would include a board-certified assistant behavior analyst (BCaBA) or a paraprofessional.

2. Though not licensed or certified at a professional level, paraprofessionals come from various occupational fields, such as education or health care (but may include other fields such as engineering and law), and are trained to assist other professionals.
3. There must be supervision of the unlicensed or noncertified paraprofessionals.
4. Policies and procedures for the supervision of paraprofessionals must be documented. A minimum of one hour of face-to-face supervision is required of the unlicensed or noncertified paraprofessional by a BCBA or licensed psychologist (or behavioral health professional) for each 10 hours of applied behavior analysis by the supervised provider. In addition, the supervisor must be onsite with the child at least one hour a month, face to face, to provide direct supervision of the paraprofessional.
5. All BCBAs and BCaBAs must maintain certification and follow recertification requirements as outlined by the Behavior Analyst Certifying Board (that is, supervision requirements for BCaBAs). In addition, BCBAs must meet the current Aetna® credentialing and recredentialing standards.
6. BCBAs and BCaBAs must meet the attached behavioral health provider criteria for all provisions that apply to the BCBA and BCaBA.
7. All BCBAs, BCaBAs and paraprofessionals must meet state requirements. If state requirements are not defined, all BCBAs, BCaBAs and paraprofessionals must meet Aetna standards.

Behavioral health facility core criteria

A. Applicability

1. These criteria apply to each facility applicant for participation and each facility participating in plans and will be enforced at the sole discretion of Aetna®.
2. Each applicant for participation as a facility must have documentation that it has met the criteria stated below.
3. Each participating facility must continue to meet the following criteria for the duration of the agreement.

E. Access and availability of services

1. Hours of operation — inpatient facility hours of operations are 24/7.
2. Facility must initiate treatment within a time frame agreeable by the referring clinician, if applicable. Facility must return treatment reports to referring clinician, if applicable, as soon as possible.

H. Insurance

Facility will maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by facilities in your state or region.

Facility must ensure that their insurance coverage extends to any and all states where care is being rendered. If facility is providing services across multiple states, the limit obtained should be the greater of any applicable state specific requirement.

The insurance coverage will cover facility and its/their agents and employees.

Facility will give Aetna® proof of insurance coverage upon request.

Facility must give Aetna at least thirty (30) days' advance notice of any cancellation or material changes to these policies, and must post notice of malpractice insurance (existing, cancellation or exemption) in a prominent location in the office.

Behavioral health provider core participation criteria and additional criteria

Behavioral health provider core criteria

A. Applicability

1. These criteria apply to each provider applicant for participation and each provider participating in plans and will be enforced at the sole discretion of Aetna®. Any exceptions to the business criteria must be approved in advance by Aetna.
2. Each applicant for participation as a provider must have documentation that the criteria stated below have been met.
3. Each participating provider must continue to meet the following criteria for the duration of participation in the Aetna plans.

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D. Availability of services and coverage

1. Availability of services
   a. Hours of operation — provider will provide office hours to members and Aetna®.
2. Coverage
   a. Provider must offer a reliable mechanism for members and other health care professionals to reach the office 24/7. Provider must meet all state and accreditation organization (NCQA or other applicable agency) standards.
   b. For outpatient services, a covering provider's office must be geographically accessible and consistent with local community patterns of care.
   c. If within a provider's scope of license, provider must have admitting privileges at a participating hospital or must have an arrangement with a participating physician who has privileges at a participating hospital.
3. Access and availability of services
   Each behavioral health care provider must schedule appointments with members, at a minimum, within the following timeframes:
   a. Emergency/urgent care: must be seen immediately (or referred to emergency room/urgent care/crisis center, as appropriate)
   b. Symptomatic/non-urgent acute care: within seven business days
   c. Routine and preventive care: initial appointment within ten business days
   d. Follow-up care:
   (i) non-prescribers of medication: within three weeks;
   (ii) prescribers of medication: within five weeks.
4. Each BH practitioner must have a reliable voicemail system or live answering service in place twenty-four (24) hours per day, seven (7) days per week. If voicemail is used, the voicemail greeting should provide direction to go to the nearest emergency department, and/or direction to call 911/988 in a crisis, and/or contact information for a licensed BH professional who is available 24 hours per day, 7 days per week.
5. **Please note:** The above appointment wait time standards also apply to behavioral health care physicians. Where more stringent, state requirements supersede the above standards and are in the **State Supplement Manual**

F. Insurance

Provider will maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by providers in your state or region.

Provider must ensure that their insurance coverage extends to any and all states where care is being rendered. If Provider is providing services across multiple states, the limit obtained should be the greater of any applicable state specific requirement.

The insurance coverage will cover provider and its/their agents and employees.

Provider will give Aetna proof of insurance coverage upon request.

Provider must give Aetna at least thirty (30) days' advance notice of any cancellation or material changes to these policies, and must post notice of malpractice insurance (existing, cancellation or exemption) in a prominent location in the office.

G. Professional competence and conduct criteria

1. Provider must not have an unsatisfactory professional liability claims history, including, but not limited to, lawsuits, arbitration, mediation, settlements or judgments and must not have engaged in any unprofessional conduct, unacceptable business practices or any other act or omission and must not have a history of involuntary termination (or voluntary termination during or in anticipation of an investigation or dismissal) of employment or any other sort of engagement as a health care professional, of reduction or restriction of duties or privileges, or of a contract to provide health care services that, in the view of Aetna and/or applicable peer review committee, may raise concerns about possible future substandard professional performance, competence or conduct.

2. In the case of an encumbered license, the applicant demonstrates to the applicable peer review committee's satisfaction that the encumbered license does not raise concern about possible future substandard professional performance, competence or conduct.

H. References

1. Provider must supply professional references as specified in the application or as requested by the applicable peer review committee.

2. The applicable peer review committee has the right to act on any information received from the provider's colleagues or other medical professionals. Provider waives any and all rights to bring any legal action relating to such information or the collection or use thereof against Aetna®; any affiliates or related or any director, officer, employee or agent thereof; or any person or entity providing a reference or information at the request of the applicable peer review committee.

Behavioral health physician core participation criteria and additional criteria

Behavioral health physician core criteria

A. Applicability

1. These criteria apply to each applicant for participation and each physician participating in plans and will be enforced at the sole discretion of Aetna. Any exceptions to the business criteria must be approved in advance by Aetna.
2. Each applicant for participation as a physician must have documentation that the criteria stated below have been met.
3. Each participating physician must continue to meet the following criteria for the duration of participation in Aetna plans.

B. General

1. The applicant must be certified by a board recognized by the American Board of Medical Specialties or the American Osteopathic Association, unless the applicant meets an exception under the Aetna policy. All exceptions must be approved by an Aetna medical director or designee.

2. If the physician is part of a group practice, all participating physicians in the group must meet these participation criteria and must agree to participate in all plans covered under the group agreement.

3. The physician must complete an application and will supply all requested information to Aetna.

D. Availability of services and coverage

1. Availability of services

   a. Hours of operation — provider will provide office hours to members and Aetna.
   b. Appointment wait-time standards — The same appointment wait time standards on page 39, section D. 3. for behavioral health care providers apply to behavioral health care physicians. Please follow those same accessibility standards.

2. Coverage

   Each physician's medical office must:

   a. Offer a reliable way for members to reach a health care professional 24/7. Physician must meet all state and accreditation organization standards (NCQA or other applicable agency).
   b. Respond to a member within 30 minutes after notification of an urgent call.
   c. Ensure that 24/7 coverage for members is rendered by a physician or arranged with another participating physician.
      For outpatient services, a covering physician's office must be geographically accessible and consistent with local community patterns of care. This helps ensure that a member doesn't have to travel more than 30 minutes to access the covering physician's services.
   d. Have admitting privileges at a participating hospital or coverage must be arranged with a participating physician who has privileges at a participating hospital.
   e. Agree to use participating providers as required in the physician agreement.

F. Insurance

Physician/physician group will maintain general and professional liability and other insurance according to state requirements. If there are no specific state requirements, then the amount should be what is typically maintained by providers in your state or region.

Physician/physician group must ensure that their insurance coverage extends to any and all states where care is being rendered. If physician/physician group is providing services across multiple states, the limit obtained should be the greater of any applicable state specific requirement.

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The insurance coverage will cover physician/physician group and its/their agents and employees.

Physician/physician group will give Aetna proof of insurance coverage upon request.

Physician/physician group must give Aetna at least thirty (30) days' advance notice of any cancellation or material changes to these policies, and must post notice of malpractice insurance (existing, cancellation or exemption) in a prominent location in the office.

H. Professional competence and conduct criteria

1. Physician must not have an unsatisfactory professional liability claims history including, but not limited to, lawsuits, arbitration, mediation, settlements or judgments, and must not have engaged in any unprofessional conduct, unacceptable business practices or any other act or omission and must not have a history of involuntary termination (or voluntary termination during or in anticipation of an investigation or dismissal) of employment or any other sort of engagement as a health care professional, of reduction or restriction of duties or privileges, or of a contract to provide health care services that, in the view of Aetna® and/or applicable peer review committee, may raise concerns about possible future substandard professional performance, competence or conduct.

2. In the case of an encumbered license, the applicant demonstrates to the applicable peer review committee's satisfaction that the encumbered license does not raise concern about possible future substandard professional performance, competence or conduct.

I. References

1. Physician must supply professional references as requested by the applicable Aetna peer review committee.

2. The applicable Aetna peer review committee has the right to act on any reference or information received from the physician's colleagues. Physician waives any and all rights to bring any legal action relating to such information or the collection or use thereof against the; any affiliates or related companies or any director, officer, employee or agent thereof; or any person or entity providing a reference or information at the request of the applicable peer review committee.

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Appendix C. NPL Committee Review of Outpatient Services

1. Factors for Adding a Service to the NPL – as applied to the NPL in 2025

	Procedure Name/Description	Cost of Treatment	High-Cost Growth	Variability in Cost & Practice	ROI	Extenuating Factors*
1.	**Whole Genome Sequencing**	**X**	**X**		**X**	

**Extenuating Factors: patient safety; clinical quality control; marked variation in provider utilization patterns; incorrect utilization; application of Clinical Policy Bulletins; standards of industry practice*

2. Factors for Retaining a Service on the NPL – as applied to the NPL in 2025

	Procedure Name/Description	ROI	Patient Safety*	Clinical Quality Control*	Marked Variation in Provider Utilization Patterns*	Incorrect Utilization*	Application of Clinical Policy Bulletins (CPB)*	Standards of Industry Practice*
1.	**Ambulance** Precertification required for transportation by fixed-wing aircraft (plane)	**X**						
2.	**Arthroplasty**	**X**						
3.	**Arthroscopic hip surgery to repair impingement syndrome including labral repair****	**X**						
4.	**Autologous chondrocyte implantation****	**X**						
5.	**BRCA Genetic Testing**				**X**			
6.	**Cardiology**	**X**						
7.	**Chiari malformation decompression surgery**	**X**						

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	Procedure Name/Description	ROI	Patient Safety*	Clinical Quality Control*	Marked Variation in Provider Utilization Patterns*	Incorrect Utilization*	Application of Clinical Policy Bulletins (CPB)*	Standards of Industry Practice*
8.	**Cochlear device and/or implantation****	**X**						
9.	**Coverage at an in-network benefit level for out-of-network provider or facility unless services are emergent.** Some plans have limited or no out-of-network benefits.							**X**
10.	**Dental implants**	**X**						
11.	**Dialysis visits**[1]					**X**		
12.	**Dorsal column (lumbar) neurostimulators: trial or implantation**	**X**						
13.	**Electric or motorized wheelchairs and scooters**							
14.	**Endoscopic nasal balloon dilation procedures****	**X**						
15.	**Functional endoscopic sinus surgery (FESS)****	**X**						
16.	**Gender affirmation surgery**	**X**						
17.	**Hyperthermic intraperitoneal chemotherapy (HIPEC)**	**X**						
18.	**Hyperbaric oxygen therapy**	**X**						
19.	**Infertility services and pre-implantation genetic testing**	**X**						

[1] Dialysis visits when a participating provider starts a request and dialysis is to be performed at a nonparticipating facility.

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	Procedure Name/Description	ROI	Patient Safety*	Clinical Quality Control*	Marked Variation in Provider Utilization Patterns*	Incorrect Utilization*	Application of Clinical Policy Bulletins (CPB)*	Standards of Industry Practice*
20.	**Lower limb prosthetics, such as microprocess or controlled lower limb prosthetics**	**X**						
21.	**Neurostimulator implantation**	**X**						
22.	**Nonparticipating freestanding ambulatory surgical facility services, when referred by a participating provider**							**X**
23.	**Orthognathic surgery procedures, bone grafts, osteotomies and surgical management of the temporomandibular joint**	**X**						
24.	**Osseointegrated implant****	**X**						
25.	**Osteochondral allograft/knee****	**X**						
26.	**Private duty nursing**	**X**						
27.	**Prostate surgery**	**X**						
28.	**Proton beam radiotherapy**	**X**						
29.	**Reconstructive or other procedures that may be considered cosmetic[2]**	**X**						
30.	**Shoulder arthroplasty including revision procedures**	**X**						

[2] Reconstructive or other procedures that maybe considered cosmetic, such as: Blepharoplasty**, Breast reconstruction/breast enlargement**, Breast reduction/mammoplasty**, Excision of excessive skin due to weight loss**, Gastroplasty /gastric bypass, Lipectomy or excess fat removal**, Surgery for varicose veins, except stab phlebectomy**

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	Procedure Name/Description	ROI	Patient Safety*	Clinical Quality Control*	Marked Variation in Provider Utilization Patterns*	Incorrect Utilization*	Application of Clinical Policy Bulletins (CPB)*	Standards of Industry Practice*
31.	**Site of service**	**X**						
32.	**Spinal procedures[3]**	**X**						
33.	**Stimulators**	**X**						
34.	**Transplants**			**X**				
35.	**Urology**	**X**						
36	**Uvulopalatopharyngoplasty including laser-assisted procedures****	**X**						
37.	**Ventricular assist devices**	**X**						
38.	**Whole exome sequencing**	**X**						
39.	**Partial hospitalization programs (PHP)**	**X**						
40.	**Applied behavioral analysis (ABA)**	**X**						
41.	**Transcranial magnetic stimulation (TMS)**	**X**						

**Extenuating Factors*
***For Commercial members, this elective procedure is subject to the medical necessity review of the procedure and the site of service.*

[3] Spinal procedures, such as: Artificial intervertebral disc surgery (cervical spine), Artificial intervertebral disc surgery (lumbar spine), Arthrodesis for spine deformity, Cervical laminoplasty**, Cervical, lumbar and thoracic laminectomy and/or laminotomy procedures**, Kyphectomy**, Laminectomy with rhizotomy, Removal of spinal instrumentation, Spinal fusion surgery, Vertebral corpectomy, Vertebroplasty/Kyphoplasty

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Appendix D. NPL Committee Voting Roster

National Precertification List (NPL) Committee Composition

Job Title	Organization	Credentials	Board Certified Specialty
VP, Clinical Strategic Operations	Strategic Clinical and Business Operations	DO	Internal Medicine
AVP, Deputy CMO	Behavioral Health	DO, FAPA, DFAACAP	Psychiatry
Senior Medical Director	Medicare UM	MD	Pediatrics
Senior Clinical Solutions Medical Director	Strategic Clinical and Business Operations	MD	Internal Medicine, Geriatric Medicine, Clinical Informatics
VP, Deputy CMO	Medical Policy & Operations	MD	Family Medicine
Executive Director	Medicare UM	MD, MBA	Family Medicine
Medical Director	Medical Policy & Operations	MD, MBA	General Surgery
Executive Director	Clinical Quality	MD	General Practice
Senior Medical Director	Medicare UM	DO, FACOI	Internal Medicine
Executive Director	Medicare UM	DO	Internal Medicine
AVP, Deputy CMO	Medicare Medical Operations	MD	Internal Medicine
AVP, Deputy CMO	Medicare UM	DO	Family Medicine
Executive Director	Commercial UM	MD	Family Medicine
Executive Director	Medical Policy & Operations	MD, MBA	Obstetrics and Gynecology
Senior Medical Director	Commercial UM	MD	Family Medicine
Senior Medical Director	Commercial UM	MD	Family Medicine, Geriatric Medicine
VP, CMO Clinical Management	Commercial UM	MD	Family Medicine
Senior Medical Director	Medical Policy & Operations	DO, MBA, MS	Family Medicine – Osteopathic Manipulative Treatment
Senior Medical Director	Commercial UM	MD, MBA	General Surgery
VP, CMO Medical Management	Medicare UM	MD, FACP, CHIE	Internal Medicine
Senior Medical Director	Medicare UM	MD, MBA, FACP, SFHM	Internal Medicine

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Appendix E. Policy and Plan Design Committee Composition

Policy and Plan Design Committee (PPDC) Composition

Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
VP, Medical Policy & Operations (Chair)	Medical Policy & Program Solutions	MD	Family Medicine
Lead Director, Project Program Management	Medical Policy & Program Solutions		
Senior Manager, Project Program Management	Medical Policy & Program Solutions		
Senior Manager, Project Management	Medical Policy & Program Solutions		
AVP, Business Operations	Medical Policy & Program Solutions		
Lead Director, Health Services	Medical Policy & Program Solutions		
Senior Manager, Project Program Management	Medical Policy & Program Solutions		
Manager, Health Services	Medical Policy & Program Solutions		
Lead Director, Project Program Management	Medical Policy & Program Solutions		
Medical Director	Medical Policy Physicians	MD, FAAP	Emergency Medicine
Medical Director	Medical Policy Physicians	MD	Obstetrics & Gynecology
Executive Director, Medical Affairs	National Quality Management	MD	General Practice
AVP, Deputy CMO	Behavioral Health	MD, DO, FAPA, DFAACAP	Psychiatry, Child and Adolescent Psychiatry
Senior Clinical Solutions MD	Behavioral Health	MME, MD, CPE, DFAPA	Psychiatry, Addiction Medicine
Senior Medical Director	Behavioral Health	MD	Psychiatry, Addiction Psychiatry
Lead Director, Project Program Management	Behavioral Health Product & Regulatory Approvals		
Senior Manager, Product Management	Behavioral Health Product & Regulatory Approvals		
Senior Manager, Product Management	Behavioral Health Product & Regulatory Approvals		
Executive Director, Strategic Programs	Service Operations		
Senior Analyst, Business Analytics	Claim & Call Policy		
Senior Analyst, Business Analytics	Claim & Call Policy		
AVP, Deputy CMO	Clinical Physician Medicare Leadership	MD	Internal Medicine

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Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
VP, CMO Medicaid	Clinical Physician Leadership (UM)	MD	Family Medicine
VP, CMO Medicare	Clinical Physician Leadership	DO	Internal Medicine
Lead Director, Corporate Compliance	Compliance (Medicare)		
Senior Manager, Corporate Compliance	Compliance (Medicare)		
Lead Director, Corporate Compliance	Compliance		
Lead Director, Corporate Compliance	Compliance		
Lead Director, Corporate Compliance	Compliance		
Lead Director, Business Compliance	Compliance		
Lead Director, Business Compliance	Compliance		
Lead Director, Health Care Quality Management	Healthcare Quality		
Lead Director, Corporate Compliance	Healthcare Quality		
Senior Manager, Clinical Health Services	Healthcare Quality		
Senior Manager, Project Program Management	Health Operations Policy Process		
Principal Counsel	Legal		
VP, Medical Economics	Finance Institutional Business		
AVP, Actuarial	Finance Institutional Business		
VP, Market Operations & Governance	Medicare		
SVP, Network Strategy & Provider Experience	Network		
Senior Manager, Project Program Management	Medical Product		
Executive Director Project & Process Management	Medical Product		
VP, Medicare Medical Operations	Medicare	MD	
Senior Claim Benefit Specialist	Medicare		
SVP, Medicare	Medicare		
Lead Director Project Program Management	Regulatory Resolution		

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Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Senior Manager, Project Management	Product & Regulatory Approvals		
Senior Manager, Project Management	Product & Regulatory Approvals		
Manager, Project Management	Product & Regulatory Approvals		
Senior Medical Director	Student Health	MD	Family Medicine
Executive Director	Student Health		
Senior Analyst, Business Analytics	Student Health		

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Appendix F. Payment Policy and Coding Committee (PPCC) Composition

Payment Policy and Coding Committee (PPCC) Composition			
Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Vice President, Deputy CMO (Chair)	Medical Policy & Operations	MD	Family Medicine
Executive Director (Vice Chair)	Medical Policy & Operations	MD	Pediatrics
Manager, Payment Policy	Medical Policy & Operations		
Sr Medical Director	Medical Policy & Operations	MD	Family Medicine
Sr Medical Director	Medical Policy & Operations	MD	Internal Medicine
Sr Medical Director	Medicare Appeals	DO	Family Medicine
Medical Director	Medical Policy & Operations	MD	Obstetrics & Gynecology
Medical Director	Medical Policy & Operations	MD	Internal Medicine, Pediatrics
Medical Director	Medical Policy & Operations	MD	Obstetrics & Gynecology
Sr Medical Director	Medicare UM	DO,MHSA, FACOI	Internal Medicine
Medical Director	Medical Policy & Operations	MD, MHP, FACOEM	Aerospace Medicine, Occupational Medicine
Medical Director	Medical Policy & Operations	MD	Ophthalmology
Sr Medical Director	Medical Policy & Operations	MD	Emergency Medicine
Sr Medical Director	Medicare UM	MD, FAAP	Pediatrics
Medical Director	Medicare UM	MD, MBA, FACS	General Surgery
Medical Director	Medical Policy & Operations	MD	Family Medicine
Executive Director	Commercial	MD	Internal Medicine
Medical Director	SME Pain Management	MD	Anesthesiology
Executive Director, National Quality Mgmt	Medical Policy & Operations	MD	General Practice
Sr Medical Director	Medicare UM	DO, FACOI	Internal Medicine
Executive Director	Commercial	MD	Obstetrics & Gynecology
AVP, Deputy CMO	Commercial	MD	Internal Medicine, Rheumatology
Sr Medical Director	Medical Policy & Operations		Internal Medicine
Executive Director	Medical Policy & Operations	MD, MBA	Obstetrics & Gynecology
Sr Medical Director	Medicare UM	MD	Emergency Medicine
Sr Medical Director	Medical Policy & Operations	DO,MBA,MS	Family Medicine, Osteopathic Manipulative Treatment
Sr Medical Director	Medicare UM	MD	Family Medicine
Medical Director	Behavioral Health	MD,DLFAP, DABPM	Psychiatry, Geriatric Psychiatry, Addiction Medicine
Medical Director	Special Investigations Unit	MD	Obstetrics & Gynecology
Medical Director	Commercial	MD	Family Medicine
Medical Director	Medicare UM	MD	Internal Medicine

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Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Medical Director	Medicaid	MD	Psychiatry, Child and Adolescent Psychiatry
Medical Director	Medical Policy & Operations	MD, MBA	General Surgery
Sr Medical Director	Medical Policy & Operations	MD	Anesthesiology
Medical Director	Medical Policy & Operations	MD	Family Medicine
Medical Director	Behavioral Health	MD	Psychiatry
Medical Director	Medical Policy & Operations	MD	Urology

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Appendix G. Clinical Policy Council Composition

Clinical Policy Council (CPC) Composition

Role	**Job Title**	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Council Chair (only votes in case of a tie)	Medical Director	Aetna Medical Affairs, Medical Policy & Operations (MPO)	MD	Anesthesiology
Council Secretary (non-voting member)	Lead Director, Business Consultant	Aetna Medical Affairs, Clinical Policy Research & Development	APRN, NP-C, PCCN-K	Adult-Gerontology
Representing Chief Medical Officer (CMO)	VP, CMO, State Programs & Medical Policy	Aetna Clinical Quality, Medical Affairs	MD	Family Medicine
Head of Clinical Policy Research & Development	Executive Director, National Quality Management	Aetna Clinical Quality, Medical Affairs, Clinical Policy Unit	MD	General Practice
Member	Medical Director	Behavioral Health	MD	Psychiatry
Member	Senior Medical Director	Care Management. CVS Community Care East Region	DO, FAAFP	Family Medicine
Member	Clinical Pharmacist	Aetna Pharmacy	PharmD	
Member	Senior Medical Director	Commercial Appeals, Aetna Medical Affairs	MD	Emergency Medicine
Member	Senior Medical Director	Commercial Fully Insured	MD, MS, MBA, FACP, DFASAM, AGAF	Gastroenterology, Addiction Medicine
Member	Executive Director, Regional Medical Director	Commercial Individual and Family Plans	MD	Family Medicine
Member	AVP, Deputy CMO	Commercial, Self-Insured, National Accounts	MD	Internal Medicine, Rheumatology
Member	Senior Medical Director - Compliance	Medical Affairs	MD	Internal Medicine
Member	Executive Medical Director of Commercial and Medicaid Appeals	Medical Affairs	MD	Internal Medicine, Pediatrics
Member	Senior Medical Director, Northeast Region	Medicaid UM	MD, JD	Internal Medicine
Member	Executive Director, Regional Medical Director	Aetna Medical Affairs, Medical Policy & Operations	MD, FAAP	Pediatrics

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Role	**Job Title**	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Member	Medical Director	Medicare Appeals	MD	Pediatrics, Allergy & Immunology
Member	Executive Director, Regional Medical Director of West and South Central Territory, Medicare	Medicare UM; Medical Affairs	DO	Internal Medicine
Member	Senior Medical Director	Medicare-Medicaid Plan/Fully Integrated Duel Eligible (MMP-FIDE), Aetna Duals Center of Excellence	MD	Preventive Medicine
Member	Executive Director, Regional Medical Director	Medical Policy & Operations, Special Case Precertification Unit	MD, MBA	Obstetrics & Gynecology
Member	Executive Medical Director	Aetna Medical Affairs	MD, MSc FRCSC	Orthopedic Surgery

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Appendix H. National Quality Oversight Committee Voting Members

National Quality Oversight Committee (NQOC) Composition

Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Senior Medical Director	Customer Clinical Program Operations	MD	Family Medicine
Executive Director, Senior Medical Director	Customer Clinical Program Operations	DO	Internal Medicine
Executive Medical Director	Medicare	MD, CHIE	Family Medicine
Executive Director	Clinical Health Services		
Supervisor, Customer Service	Behavioral Health, Employee Assistance Program		
Senior Principal Clinical Leader	Clinical Solutions		
Senior Manager	Corporate Compliance		
Senior Medical Director	Behavioral Health	MD	Psychiatry, Addiction Psychiatry
Senior Clinical Solutions Medical Director	Customer Clinical Program Operations	MD	Internal Medicine
Medical Director	Customer Clinical Program Operations	MD	Family Medicine
Lead Director	Health Care Quality Management		
Medical Director	Customer Clinical Program Operations	MD	Internal Medicine
Senior Medical Director	Strategic Clinical and Business Operations	MD	Internal Medicine, Geriatric Medicine, Clinical Informatics
Senior Manager, Business Consultant	Enterprise Accounts		
Lead Director	Network Operations		
Lead Director	Health Care Quality Management		
Clinical Pharmacy Manager	Clinical Pharmacy Product Operations	RPh	
VP, Territory Network Lead	Network Provider Services		
Medical Director	Customer Clinical Program Operations	MD	Pediatrics
Senior Medical Director	Medicare	MD	Pediatrics
Executive Director	Health Care Quality Management		
Executive Director	Clinical Service Operations		
Lead Director	Provider Relations		

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Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Medical Director	Customer Clinical Program Operations	MD, MPH, FACPM	Public Health and General Preventive Medicine
Texas HMO Enrollee	External		
Senior Manager	Health Care Quality Management		
Lead Director, Quality and Compliance Operations	Clinical Solutions	MSW, LSW	
Principal Clinical Leader	Behavioral Health, EAP	RN	
Medical Director	Customer Clinical Program Operations	MD	Obstetrics and Gynecology
Supervisor, Claim Processing	Service Operations		
Senior Principal Leader	Clinical Services Utilization Management		
Lead Director, Business Consultant	Clinical Services Utilization Management Operations		
Senior Medical Director	Behavioral Health	MD	Psychiatry
Senior Medical Director	Customer Clinical Program Operations	MD, MBA, FACP, SFHM	Internal Medicine
Executive Director	Customer Clinical Program Operations	MD	Family Medicine
Sr. Clinical Solutions Medical Director	Customer Clinical Program Operations	MD	Internal Medicine
Senior Manager	Behavioral Health Clinical Health Services		
Lead Director	Health Care Quality Management		
South Carolina HMO Enrollee	External		
Lead Director	Network Management		
Senior Manager, Project Program Management	Complaints, Grievances, and Appeals		
Lead Director, Quality and Compliance Operations	Clinical Solutions	MS, LPC, CN, LPN	
Texas Participating Practitioner	External		
Lead Director	Behavioral Health Clinical Health Services		
Medical Director	Medicare	MD	Emergency Medicine
AVP, Quality Management	Aetna Clinical Solutions	DC	
Manager, Project Management	Service Operations		

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Job Title	**Organization**	**Credentials** (if applicable)	**Board Certified Specialty** (if applicable)
Lead Director	Health Care Quality Management		
Medical Director	Medical Policy & Operations	MD, MBA	General Surgery
AVP, Clinical Health Services	Behavioral Health Clinical Health Services	LMHC	
Medical Director	Customer Clinical Program Operations	MD, MS, FACP, FIDSA, FISAC	Internal Medicine, Infectious Disease
Senior Manager	Network Management		
Lead Director	Network Management		

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Appendix I. National Quality Advisory Committee Voting Members

National Quality Advisory Committee (NQAC) Composition	
Aetna Voting Members	**Joint Venture Voting Members**
Medical Director, Emergency Medicine	VP, CMO
Medical Director, Psychiatrist	Chief Medical Officer
Medical Director, Family Medicine	Chief Medical Officer
Specialties of external M/S voting members	**Specialties of external MH/SUD voting members**
Family Medicine	Psychiatrist
Family Medicine	LCSW
Internal Medicine	LCSW
Family Medicine	Neuropsychiatrist
Obstetrics/Gynecology	Psychologist
Cardiology	Psychiatric Nurse Practitioner
Ophthalmology	Licensed Behavior Analyst
Internal/Hospital Medicine	Psychologist
Interventional Radiology	Psychiatrist
Internal Medicine	Psychiatrist
Family Medicine	Psychiatrist
General Surgery	Psychiatrist
Family Medicine	Psychiatrist
Family Medicine	Licensed Professional Counselor, Substance Abuse Treatment Practitioner
Obstetrics/Gynecology	Mental Health Therapist
Pediatrics/Internal Medicine	
Other voting members	
Virginia enrollee (HMO)	
Virginia enrollee (PPO)	

Appendix J. Credentialed and Non-Credentialed Provider Types

Practitioner types Aetna will credential:

As documented in QM 54, Aetna or its delegate will credential practitioners when an independent relationship, which means Aetna lists the practitioner by name in the network directory, where Aetna members select participating providers, exists with:

- Practitioners (whether or not they are Facility-Based) who provide care to members as a result of participating practitioners making a direct referral to the practitioner
- Practitioners who provide care outside of the inpatient or outpatient hospital setting or Freestanding Facilities
- Practitioners who are Facility-Based, but who are providing care as primary care physicians to Aetna members
- Practitioners who are Facility-Based, but also provide consultation in an office-based practice outside the hospital
- Practitioners who provide Telehealth Services
- Oral Surgeons who provide care under the organization's medical benefits
- Rental network practitioners who are used as a part of the organization's primary network and the organization has members who reside in the rental network area
- Rental network practitioners who are specifically for out-of-area care and members may see only those practitioners
- Rental network practitioners who are specifically for out-of-area care and there is an incentive communicated to members to see rental network practitioners

As documented in QM 53, Aetna or its delegate will credential Allied Health Practitioners and Allied Behavioral Health Practitioners when an independent relationship, which means Aetna lists the practitioner by name in the network directory, where Aetna members select participating providers, exists with:

- Practitioners, who are licensed, registered, nationally or state certified or otherwise qualified by law to practice independently
- Practitioners who are not specifically excluded from credentialing under Aetna credentialing policies
- Practitioners that provide outpatient mental health or chemical dependency services to Aetna members
- Practitioners who provide Telehealth Services
- Rental network practitioners who are used as a part of the organization's primary network and the organization has members who reside in the rental network area
- Rental network practitioners who are specifically for out-of-area care and members may see only those practitioners
- Rental network practitioners who are specifically for out-of-area care and there is an incentive communicated to members to see rental network practitioners

Organizational provider types Aetna will credential:

As documented in Provider Data Services Procedure P300-086.000, which is referenced in QM 51, Aetna will credential these organizational provider types:

- Cardiac catheterization lab
- Children's hospital
- Convalescent facility
- Durable medical equipment provider
- Freestanding surgery center
- Home care agency
- Hospital or rehabilitation hospital
- Long term care hospital
- Nursing home
- Skilled nursing facility
- Voluntary interruption of pregnancy center
- Chemical dependency or substance use disorder facility (inpatient and/or outpatient)
- Community mental health center
- Crisis stabilization program
- Intensive outpatient program/clinic
- Partial hospitalization program
- Psychiatric hospital
- Residential treatment facility

Non-credentialed provider types Aetna will assess in states where there is no state credentialing requirement:

As documented in Network Policy AETPENO-072002, Aetna will assess these facility and ancillary providers prior to finalizing network contracting:

- Ambulance medical transportation (land, air, water)
- Birthing centers (freestanding)
- Blood bank
- Comprehensive outpatient rehabilitation facility
- Diabetic self-management outpatient providers
- Diabetic treatment center or facility
- Diagnostic general radiology, mammography center, ultrasound center
- Dialysis facility
- Federally qualified health center (FQHC)
- Hospice (freestanding)
- Hospital based physician groups/individuals not employed by a hospital
- Hyperbaric oxygen therapy facility
- Independent diagnostic testing facility, electrocardiogram monitoring, pacemaker monitoring, and cardiac event detection
- Infusion center
- Laboratory test/draw sites
- Lithotripsy (mobile)
- Mobile units (portable radiology, mammography, ultrasound, EKG)

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- MRI center, PET scan, CT scan, nuclear medicine
- Nutrition/Dietitian facility
- Occupational medicine clinic
- Oncology treatment center
- Opioid treatment program/center
- Optical/vision facility
- Orthotics and prosthetics providers
- Pain management center
- Physical, occupational, or speech therapy facility
- Rural health clinic
- Sleep diagnostic center
- Urgent care
- Walk-in clinic or retail clinic
- Wellness clinic, worksite/employer-based clinic

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Appendix K. National Network Availability and Accessibility Standards

1. QM 10 National standards for numeric availability

Provider Types	Provider-to-Member Numeric Availability Standard
Internal Medicine	2:1,000
General Practice & Family Practice	2:1,000
Pediatric	2:1,000
M/S High-Volume: OB/GYN	2:1,000
M/S High-Impact: Oncology	0.2:1,000
MH/SUD High-Volume: Masters Prepared Therapist	2:3,000
MH/SUD High-Impact: Psychiatrist	1:2,000
Psychologist	1:3,000
Psychiatrists Treating Children	1:2,000
MH/SUD Ambulatory Facility	1:40,000
MH/SUD Inpatient Facility	1:40,000
MH/SUD Residential Treatment Facility	1:40,000

2. QM 10 National standards for geographic availability of providers

Population Density	Geographic Standard
M/S Internal Medicine	
Urban	2:10 miles
Suburban	2:15 miles
Rural	2:45 miles
M/S General Practice and Family Practice	
Urban	2:10 miles
Suburban	2:15 miles
Rural	2:45 miles
M/S Pediatric (Membership: 17 years and younger)	
Urban	2:10 miles
Suburban	2:15 miles
Rural	2:45 miles
M/S High-Volume Specialist: Ob/Gyn (Membership: females 13 years and older)	
Urban	2:10 miles
Suburban	2:15 miles
Rural	2:45 miles
M/S High-Impact Specialist: Oncology	
Urban	1:10 miles
Suburban	1:20 miles
Rural	1:45 miles
MH/SUD Psychiatrist (High-Impact Practitioner)	
Urban	1:10 miles
Suburban	1:10 miles
Rural	1:40 miles

Population Density	Geographic Standard
MH/SUD Psychologist	
Urban	1:10 miles
Suburban	1:10 miles
Rural	1:40 miles
MH/SUD Masters Prepared Therapist (High-Volume Practitioner)	
Urban	1:10 miles
Suburban	1:10 miles
Rural	1:40 miles
MH/SUD Psychiatrist Treating Children (Membership: 17 years and younger)	
Urban	1:10 miles
Suburban	1:10 miles
Rural	1:40 miles
MH/SUD Ambulatory Facility	
Urban	1:25 miles
Suburban	1:25 miles
Rural	1:45 miles
MH/SUD Inpatient Facility	
Urban	1:25 miles
Suburban	1:25 miles
Rural	1:45 miles
MH/SUD Residential Treatment Facility	
Urban	1:50 miles
Suburban	1:50 miles
Rural	1:90 miles

3. QM 07 National standards for provider accessibility

Practitioner Type	Appointment Type	Standard
M/S Primary care physicians and high-impact and high-volume specialists	Emergency and urgently needed services	Immediately (all members requiring emergency or urgently needed services are seen immediately or referred to the emergency room as appropriate).
M/S Primary care physicians	Regular or routine care appointments	Within 7 business days
M/S Primary care physicians	Preventive care visit	Within 30 business days
M/S High-impact and high-volume specialists	Regular or routine care appointments	Within 30 business days
M/S Primary care physicians and high-impact and high-volume specialists	After-hours care	Must have a reliable twenty-four (24) hours a day, seven (7) days-a-week answering service or machine with a beeper or paging system.

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Practitioner Type	Appointment Type	Standard
All MH/SUD practitioners (including high-impact and high-volume practitioners)	Emergency and urgently needed services	Immediately (all members requiring emergency or urgently needed services are seen immediately or referred to the emergency room/urgent care/crisis center as appropriate).
All MH/SUD practitioners (including high-impact and high-volume practitioners)	Non-emergency/non-urgent care that requires medical attention	Within 7 business days
All MH/SUD practitioners (including high-impact and high-volume practitioners)	Initial regular or routine office visit	Within 10 business days
MH/SUD prescribing practitioners (including high-impact practitioners)	Follow up routine office visit	Within 35 calendar days
MH/SUD practitioners who do not prescribe medication (including high-volume practitioners)	Follow up routine office visit	Within 21 calendar days
MH/SUD prescribing practitioners (including high-impact practitioners)	After-hours care	Each practitioner must have a reliable live answering service or voicemail system in place twenty-four (24) hours per day, seven (7) days per week. In addition, prescribing practitioners are required to have a designated practitioner backup and/or an answering service and/or a machine with a beeper/ paging system in place 24 hours per day, 7 days per week.
MH/SUD practitioners who do not prescribe medication (including high-volume practitioners)	After-hours care	Each practitioner must have a reliable live answering service or voicemail system in place twenty-four (24) hours per day, seven (7) days per week. In addition, non-prescribing practitioners are required to have a voicemail greeting which provides contact information for a licensed BH professional who is available 24 hours per day, 7 days per week; and/or direction to go to the nearest emergency department; and/or direction to call 911/988 in a crisis.

Clinical Policy Bulletin 1099 Narsoplimab-wuug (Yartemlea)
aetna.com/cpb/medical/data/1000_1099/1099.html

Example: Medical/Surgical Treatment Determined to be Medically Necessary

Treatment

Narsoplimab-wuug (Yartemlea) for hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).

Step 1: Identify the Clinical Question

Can narsoplimab-wuug be considered medically necessary for treatment of TA-TMA?

The policy team first defines the specific indication under review, including the target patient population, disease characteristics, and proposed use.

Step 2: Compile Evidence Sources

The policy team assembles relevant evidence from multiple sources, including:

- FDA approval documents and prescribing information.
- Peer-reviewed clinical studies.
- Pivotal trial data.
- Expanded access program data.
- Specialty medical literature regarding disease pathophysiology and treatment.
- Clinical references describing diagnosis and management of TA-TMA.

For this review, evidence included the pivotal trial by Khaled et al., expanded-access outcomes reported by Schoettler et al., comparative survival analyses, FDA review materials, and other referenced literature.

Step 3: Assess the Evidence

The collected evidence is evaluated for:

- Study design.
- Patient population.
- Clinical relevance.

- Consistency of findings.
- Safety profile.
- Magnitude of benefit.

Reviewers noted:

- TA-TMA is a serious, life-threatening post-transplant complication.
- FDA approval was granted for patients age 2 years and older.
- Clinical studies demonstrated meaningful improvements in laboratory markers, organ function, and survival.
- Expanded-access data supported effectiveness in real-world settings.
- The safety profile was characterized and considered manageable within the treatment setting.

Step 4: Interpret the Evidence

The policy team interprets the evidence in the context of the disease.

Reviewers concluded:

- TA-TMA is associated with substantial morbidity and mortality.
- The mechanism of action is biologically plausible and aligns with current understanding of disease pathogenesis.
- Available clinical data consistently demonstrated treatment response and survival benefit.
- The FDA determined that the overall benefit-risk profile was favorable for the approved indication.

Based on this assessment, the evidence was considered sufficient to establish clinical effectiveness for TA-TMA.

Step 5: Translate Evidence into Coverage Criteria

The evidence is then converted into objective, operational coverage requirements that identify members most consistent with the studied population.

Examples include:

- Age 2 years or older.

- Laboratory evidence of TA-TMA, including thrombocytopenia and microangiopathic hemolysis.
- ADAMTS13 activity ≥10% to distinguish TA-TMA from thrombotic thrombocytopenic purpura.
- Restrictions on concurrent use with alternative complement inhibitors or defibrotide.
- Reauthorization criteria requiring objective evidence of clinical improvement.

These criteria directly reflect the diagnostic and treatment parameters evaluated in the supporting evidence.

Step 6: Coverage Determination

Based on the totality of evidence, including FDA approval, clinical trial outcomes, survival data, safety information, and clinical relevance, narsoplimab-wuug was determined to be **medically necessary** for appropriately selected members with TA-TMA.

Example: Medical/Surgical Use Determined to be Experimental, Investigational, or Unproven Treatment

Narsoplimab-wuug for any indication other than TA-TMA.

Step 1: Identify the Clinical Question

Can narsoplimab-wuug be considered medically necessary for another disease or condition not addressed in the FDA-approved indication?

Step 2: Compile Evidence Sources

The same types of sources are reviewed:

- Published literature.
- Clinical studies.
- Regulatory information.
- Professional guidelines.
- Available safety and effectiveness data.

Step 3: Assess the Evidence

Reviewers evaluate:

- Whether adequate clinical studies exist.
- Whether outcomes demonstrate meaningful clinical benefit.
- Whether findings are reproducible and generalizable.
- Whether there is sufficient evidence to establish effectiveness.

Step 4: Interpret the Evidence

For non-TA-TMA indications, reviewers may find:

- Limited or preliminary evidence.
- Small uncontrolled studies.
- Lack of confirmatory clinical trials.
- Absence of regulatory approval.
- Uncertainty regarding clinical benefit.

Step 5: Apply EIU Standards

The same factors used in all policy reviews are applied:

- Strength and quality of evidence.
- Demonstrated safety.
- Demonstrated effectiveness.
- Clinical acceptance.
- Regulatory status.

Step 6: Coverage Determination

Because effectiveness has not been established for indications outside the approved TA-TMA population, those uses are classified as **experimental, investigational, or unproven**.