Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization

Benefit Classifications/Subclassifications

- **In-network Inpatient**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Plan Terms and/or Description of NQTL:

Precertification is a utilization review service performed by licensed healthcare professionals before inpatient admissions, select ambulatory procedures and outpatient services under the Outpatient-All Other classification, to determine medical necessity and appropriateness of treatment. The member's certificate of coverage identifies whether precertification is required and what the consequences are of failing to obtain precertification.

For in-network benefits, precertification applies to:

- Services on the Aetna Participating Provider Precertification List,
- Services on the Aetna Behavioral Health Precertification List, and
- Services that require precertification under the terms of the member's plan (typically applicable to self-insured plans).

It is the participating provider's responsibility to seek precertification.

The Aetna Participating Provider Precertification List and Aetna Behavioral Health Precertification List are referred to collectively as the National Precertification List (NPL). The NPL in effect as of the date of this document is included in the Appendix to UM NQTLs. It is subject to change. The most current version is publicly available at **www.aetna.com/health-care-professionals/precertification/precertification-lists.html.**

For out-of-network benefits, precertification applies to the services listed in the member's certificate of coverage, referred to in this document as the Member Precertification List (MPL). It is the member's responsibility to seek precertification.

Medical/Surgical (M/S) services NQTL applies to:	**Mental Health and Substance Use Disorder (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

Certificate of Coverage language:

Medical necessity[and, precertification] requirements

Your plan pays for its share of the expense for **covered services** only if the general requirements are met. They are:

- The service is **medically necessary**
- [For in-network benefits, you get the service from a **network [provider]**]
- [You or your **[provider] precertifies** the service when required]

[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. **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,** 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**
- **Stays in a skilled nursing facility]**

[Outpatient –

- [ART services]
- Complex imaging
- [Comprehensive **infertility** services]
- 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**
- Non-emergency transportation by airplane
- Outpatient back **surgery** not performed in a **[physician's]** office
- [Obesity (bariatric) **surgery]**
- Partial hospitalization treatment **– mental health 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.**

Our clinical policy bulletins explain our policy for specific services and supplies. We use these bulletins and other resources to help guide individualized coverage decisions under our plans. You can find the bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]

Glossary:

Precertification, precertify

Pre-approval that you or your [provider] receives from us before you receive certain **covered services.** This may include a determination by us as to whether the service is **medically necessary** and eligible for coverage.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors:
Factors used in designing the NQTL

Factors for Adding a Service to the NPL:

[redacted]

Extenuating Factors: [redacted]

[redacted]

Factors for Retaining a Service on the NPL:

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources: *Processes, strategies and/or evidentiary standards used to design and apply the NQTL*
Process for Developing the National Precertification List (NPL): The NPL is used by participating providers to identify which MH/SUD and M/S services require precertification for INN coverage. The NPL Committee is responsible for determining which services to add, retain or remove from the NPL. It comprises clinicians and other subject matter experts representing both MH/SUD and M/S expertise. See Appendix to UM NQTLs for the NPL Committee composition. Proposed additions or changes to the NPL are submitted to the NPL Committee. The Committee considers the factors listed above and decides whether to add or remove the service. Also, the 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. The process is comprehensively described in the NPL Committee Policy & Procedure. Evidentiary Standards for Developing the NPL: • Medicare rates • Internal claims database analysis • Internal analysis of administrative costs • Clinical guidelines and standards of practice. (These depend on the service under consideration and would include, by way of example, the most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins.) Process and Standards for Performing Precertification:

Aetna's processes for precertifying services that are on the NPL are designed in accordance with National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, and applicable state and federal law. In brief, precertification requests and supporting documentation are reviewed by clinical support staff who are not licensed health care providers. They can make coverage approvals that do not require clinical review, and 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 who are Registered Nurses (RNs), licensed clinical social workers (LSCWs) or physicians. If a licensed clinician is unable to approve coverage, the clinician refers the request to a Medical Director who is a physician or to a consulting psychiatrist/ psychologist/ board certified behavior analyst-doctoral (BCBA-D) for further review and action. Consulting psychiatrists/psychologists/BCBA-D use the available clinical information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) The precertification determination is made and communicated to the provider/member according to the established timeframes for urgent or non-urgent requests. In some circumstances the treating provider may have a peer-to-peer consultation with a physician.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Comparability and Stringency Analysis: *Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation*
As Written: The same factors and sources, and the same National Precertification List Policy and Procedure, apply to MH/SUD and M/S benefits in deciding which services to add to, retain or remove from the National Precertification list. The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling precertification requests for MH/SUD and M/S benefits. Thus, as written this NQTL is applied comparably, and not more stringently, to MH/SUD benefits.

Plan/Issuer Response – In Operation:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

In Operation: The following measures are used to assess comparability and stringency:

Evaluation of determinations adding to or removing MH/SUD and M/S services from the NPL:
Precertification is required for all inpatient admissions for both MH/SUD and M/S services. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) Precertification is not required for any MH/SUD or M/S Outpatient-Office Visits. As for Outpatient-All Other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 34 categories of M/S services, and no new MH/SUD services have been added to the NPL in the past 5 years (since the framework for inclusion on the NPL was formalized). In the NPL Committee's 2022 annual retention review, no MH/SUD or M/S services that met the ROI were removed from the NPL. For services that did not meet the ROI, two M/S services were retained on the NPL due to clinical quality control concerns (kyphectomy) and marked variation in utilization patterns (motorized scooters), and one MH/SUD service was retained on the list due to clinical quality control concerns (partial hospitalization). From this information it is clear that the factors and sources used to add to, retain or remove a service from the NPL are comparable, and not more stringent, for MH/SUD services.

Denial Rates and turnaround times for INN MH/SUD and M/S precertifications: [redacted]

In-Network Precertification Decisions	**Inpatient M/S**	**Inpatient MH/SUD**	**Outpt M/S**	**Oupt MH/SUD**
Total Decisions	[redacted]	[redacted]	[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]	[redacted]	[redacted]
Overall Percent Denied	[redacted]	[redacted]	[redacted]	[redacted]
Average Decision TAT (Days)	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Internal Quality Reviews and Inter-Rater Reliability assessments: The IQR/IRR process described in [redacted] provides a way to evaluate whether utilization review of MH/SUD and M/S 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 an individual's results do not meet the goal of 90%. Corrective action plans and appropriate monitoring are also established for business areas with a final score below the target of 95%. The IQR and 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. Some Behavioral Health and Medical individual clinicians and business areas fell below the goal and were identified for corrective actions should they continue to score below the goal. These IQR/IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services. [redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
The factors and sources used in determining what INN services are subject to precertification, and in handling precertification requests, are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents (submitted with production as separate exhibits)
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization

Benefit Classifications/Subclassifications

- **In-network Outpatient All Other subclassification**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Plan Terms and/or Description of NQTL:
Precertification is a utilization review service performed by licensed healthcare professionals before inpatient admissions, select ambulatory procedures and outpatient services under the Outpatient-All Other classification, to determine medical necessity and appropriateness of treatment. The member's certificate of coverage identifies whether precertification is required and what the consequences are of failing to obtain precertification.

For in-network benefits, precertification applies to:

- Services on the Aetna Participating Provider Precertification List,
- Services on the Aetna Behavioral Health Precertification List, and
- Services that require precertification under the terms of the member's plan (typically applicable to self-insured plans).

It is the participating provider's responsibility to seek precertification.

The Aetna Participating Provider Precertification List and Aetna Behavioral Health Precertification List are referred to collectively as the National Precertification List (NPL). The NPL in effect as of the date of this document is included in the Appendix to UM NQTLs. It is subject to change. The most current version is publicly available at **www.aetna.com/health-care-professionals/precertification/precertification-lists.html.**

For out-of-network benefits, precertification applies to the services listed in the member's certificate of coverage, referred to in this document as the Member Precertification List (MPL). It is the member's responsibility to seek precertification.

Medical/Surgical (M/S) services NQTL applies to:	Mental Health and Substance Use Disorder (MH/SUD) services NQTL applies to:
INN Outpatient-All Other: Too numerous to list -- see the Participating Provider Precertification List at the Appendix to UM NQTLs	**INN Outpatient-All Other:** • Applied Behavioral Analysis (ABA) for Autism Spectrum Disorder • Transcranial Magnetic Stimulation • Partial Hospitalization (PHP) • Gender Affirmation Surgery (These are also listed in the Appendix to UM NQTLs)

Certificate of Coverage language:

Medical necessity[and, precertification] requirements

Your plan pays for its share of the expense for **covered services** only if the general requirements are met. They are:

- The service is **medically necessary**
- [For in-network benefits, you get the service from a **network [provider]**]
- [You or your **[provider] precertifies** the service when required]

[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. **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,** 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**
- **Stays in a skilled nursing facility]**

[Outpatient –
- [ART services]
- Complex imaging
- [Comprehensive **infertility** services]
- 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**
- Non-emergency transportation by airplane
- Outpatient back **surgery** not performed in a **[physician's]** office
- [Obesity (bariatric) **surgery]**
- Partial hospitalization treatment **– mental health 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.**

Our clinical policy bulletins explain our policy for specific services and supplies. We use these bulletins and other resources to help guide individualized coverage decisions under our plans. You can find the bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]

Glossary:

Precertification, precertify

Pre-approval that you or your [provider] receives from us before you receive certain **covered services.** This may include a determination by us as to whether the service is **medically necessary** and eligible for coverage.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors: *Factors used in designing the NQTL*
Factors for Adding a Service to the NPL: [redacted] **Extenuating Factors**: [redacted]

[redacted]

[redacted]

<u>Factors for Retaining a Service on the NPL</u>:

- [redacted]

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources:
Processes, strategies and/or evidentiary standards used to design and apply the NQTL

Process for Developing the National Precertification List (NPL):
The NPL is used by participating providers to identify which MH/SUD and M/S services require precertification for INN coverage. The NPL Committee is responsible for determining which services to add, retain or remove from the NPL. It comprises clinicians and other subject matter experts representing both MH/SUD and M/S expertise. See Appendix to UM NQTLs for the NPL Committee composition. Proposed additions or changes to the NPL are submitted to the NPL Committee. The Committee considers the factors listed above and decides whether to add or remove the service. Also, the 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. The process is comprehensively described in the NPL Committee Policy & Procedure.

Evidentiary Standards for Developing the NPL:

- Medicare rates
- Internal claims database analysis
- Internal analysis of administrative costs
- Clinical guidelines and standards of practice. (These depend on the service under consideration and would include, by way of example, the most currently available versions of CMS Coverage Determinations and Medicare Benefit Policy Manual, MCG Health guidelines, National Comprehensive Cancer Network (NCCN) guidelines, American Society of Addiction Medicine (ASAM) Criteria, CALOCUS/LOCUS guidelines, and Aetna Clinical Policy Bulletins.)

Process and Standards for Performing Precertification:

Aetna's processes for precertifying services that are on the NPL are designed in accordance with National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, and applicable state and federal law. In brief, precertification requests and supporting documentation are reviewed by clinical support staff who are not licensed health care providers. They can make coverage approvals that do not require clinical review, and 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 who are Registered Nurses (RNs), licensed clinical social workers (LSCWs) or physicians. If a licensed clinician is unable to approve coverage, the clinician refers the request to a Medical Director who is a physician or to a consulting psychiatrist/ psychologist/ board certified behavior analyst-doctoral (BCBA-D) for further review and action. Consulting psychiatrists/psychologists/BCBA-D use the available clinical information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) The precertification determination is made and communicated to the provider/member according to the established timeframes for urgent or non-urgent requests. In some circumstances the treating provider may have a peer-to-peer consultation with a physician. [redacted]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Comparability and Stringency Analysis: *Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation*
As Written: The same factors and sources, and the same National Precertification List Policy and Procedure, apply to MH/SUD and M/S benefits in deciding which services to add to, retain or remove from the National Precertification list. The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling precertification requests for MH/SUD and M/S benefits. Thus, as written this NQTL is applied comparably, and not more stringently, to MH/SUD benefits.

Plan/Issuer Response – In Operation:

Comparability and Stringency Analysis: *Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation*
In Operation: The following measures are used to assess comparability and stringency: Evaluation of determinations adding to or removing MH/SUD and M/S services from the NPL: Precertification is required for all inpatient admissions for both MH/SUD and M/S services. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) Precertification is not required for any MH/SUD or M/S Outpatient-Office Visits. As for Outpatient-All Other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 34 categories of M/S services, and no new MH/SUD services have been added to the NPL in the past 5 years (since the framework for inclusion on the NPL was formalized). In the NPL Committee's 2022 annual retention review, no MH/SUD or M/S services that met the ROI were removed from the NPL. For services that did not meet the ROI, two M/S services were retained on the NPL due to clinical quality control concerns (kyphectomy) and marked variation in utilization patterns (motorized scooters), and one MH/SUD service was retained on the list due to clinical quality control concerns (partial hospitalization). From this information it is clear that the factors and sources used to add to, retain or remove a service from the NPL are comparable, and not more stringent, for MH/SUD services. Denial Rates and turnaround times for INN MH/SUD and M/S precertifications: [redacted]

In-Network Precertification Decisions	Inpatient M/S	Inpatient MH/SUD		Outpatient M/S	Outpatient MH/SUD
Total Decisions	[redacted]				
Denied Decisions	[redacted]				
Overall Percent Denied	[redacted]				
Average Decision TAT (Days)	[redacted]				

[redacted]

Internal Quality Reviews and Inter-Rater Reliability assessments: The IQR/IRR process described in [redacted] provides a way to evaluate whether utilization review of MH/SUD and M/S 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 an individual's results do not meet the goal of 90%. Corrective action plans and appropriate monitoring are also established for business areas with a final score below the target of 95%. The IQR and 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. Some Behavioral Health and Medical individual clinicians and business areas fell below the goal and were identified for corrective actions should they continue to score below the goal. These IQR/IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services. [redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
The factors and sources used in determining what INN services are subject to precertification, and in handling precertification requests, are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents (submitted with production as separate exhibits)
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization
Benefit Classifications/Subclassifications

- **Out-of-network Inpatient**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Description of NQTL: The Member Precertification List (MPL) is part of the certificate of coverage which is filed with each State department of insurance. 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. The analysis below is for Aetna's standard certificate of coverage.

Medical/Surgical (M/S) services NQTL applies to:	**Mental Health and Substance Use Disorder (MH/SUD) services NQTL applies to:**

OON Inpatient: • Stays in a hospital • Stays in a rehabilitation facility • Stays in a hospice facility • Stays in a skilled nursing facility	**OON Inpatient:** • Stays in a hospital • Stays in a residential treatment facility

Certificate of Coverage language:

Medical necessity[and, precertification] requirements

Your plan pays for its share of the expense for **covered services** only if the general requirements are met. They are:

- The service is **medically necessary**
- [For in-network benefits, you get the service from a **network [provider]**]
- [You or your **[provider] precertifies** the service when required]

[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. **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.] 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**
- **Stays** in a **skilled nursing facility**]

[Outpatient –

- [ART services]
- Complex imaging
- [Comprehensive **infertility** services]
- 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**
- Non-emergency transportation by airplane
- Outpatient back **surgery** not performed in a **[physician's]** office
- [Obesity (bariatric) **surgery]**
- Partial hospitalization treatment – **mental health 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**.

Our clinical policy bulletins explain our policy for specific services and supplies. We use these bulletins and other resources to help guide individualized coverage decisions under our plans. You can find the bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html]

Glossary:

Precertification, precertify

Pre-approval that you or your **[provider]** receives from us before you receive certain **covered services**. This may include a determination by us as to whether the service is **medically necessary** and eligible for coverage.

Schedule of Benefits language:

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 benefit reduction of [0%-50%] up to a maximum of [$100-$500] for each type of **covered occurrence.**
- **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**]

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.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:
Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors:
Factors used in designing the NQTL

The factors used in designing the original Member Precertification List cannot be listed because the MPL has existed long before the MHPAEA regulations were issued and there was not an explicit list of factors or processes. Effective September 2023, the factors and process for adding or removing a service from the MPL have been formalized in the **Member Precertification List Policy and Procedure**. The factors are:

Adding a Service, Drug or Device to the MPL:

[redacted]

[redacted]

[redacted]

Removing a Service, Drug or Device from the MPL:

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources:
Processes, strategies and/or evidentiary standards used to design and apply the NQTL

Process for Developing the MPL**:**
The Policy and Plan Design Committee (PPDC), a group of clinicians, product managers, legal counsel, compliance leads, and other subject matter experts representing both MH/SUD and M/S expertise, is responsible for deciding whether to add or remove services from the MPL. See Appendix to the UM NQTLs for the PPDC composition**.**

PPDC members and business partners may propose changes to the MPL. The PPDC considers the factors listed above and votes on whether to approve a change. Any 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. The process is comprehensively described in the **Aetna Member Precertification List (MPL) Policy & Procedure.**

Evidentiary Standards for Developing the MPL:

- Medicare rates
- Internal analysis of administrative costs
- Clinical guidelines and standards of practice

Process and Standards for Performing Precertification:
Aetna's processes for precertifying services that are on the MPL are designed in accordance with National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, and applicable state and federal law. In brief, precertification requests and supporting documentation are reviewed by clinical support staff who are not licensed health care providers. They can make coverage approvals that do not require clinical review, and 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 who are RNs, licensed behavioral health clinicians. If a licensed clinician is unable to approve coverage, the clinician refers the request to a Medical Director who is a physician or to a consulting psychiatrist/ psychologist/ board certified behavior analyst-doctoral (BCBA-D) for further review and action. Consulting psychiatrists/psychologists/BCBA-D use the available clinical

information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) The precertification determination is made and communicated to the provider/member according to the established timeframes for urgent or non-urgent requests. In some circumstances the treating provider may have a peer-to-peer consultation with a physician. [redacted]

- [redacted]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

As Written: The same factors and sources, and the same Member Precertification List Policy and Procedure, apply to MH/SUD and M/S benefits in deciding which services to add to or remove from the Member Precertification list. The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling precertification requests for MH/SUD and M/S benefits. Thus, as written this NQTL is applied comparably, and not more stringently, to
MH/SUD benefits.

Plan/Issuer Response – In Operation:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

In Operation: The following measures are used to assess comparability and stringency:

Evaluation of determinations adding to or removing MH/SUD and M/S services from the MPL: Precertification is required for all inpatient admissions for both MH/SUD and M/S services. Precertification is not required for any MH/SUD or M/S Outpatient-Office Visits. As for Outpatient-All Other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 13 *categories* of M/S services. From this information it can be inferred that the factors and sources used to add or remove a service from the MPL are not being applied more stringently to MH/SUD services.

Denial Rates and turnaround times for OON MH/SUD and M/S precertifications: [redacted]

Out-of-Network Precertification Decisions	Inpt M/S	Inpt MH/SUD	Outpatient M/S	Outpatient MH/SUD
Total Decisions	[redacted]	[redacted]	[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]	[redacted]	[redacted]
Overall Percent Denied	[redacted]	[redacted]	[redacted]	[redacted]
Average Decision TAT (Days)	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Internal Quality Reviews and Inter-Rater Reliability assessments: The IQR/IRR process described in [redacted] provides a way to evaluate whether utilization review of MH/SUD and M/S 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 the goal of 90%. Corrective action plans and appropriate monitoring are also established for business areas with a final score below the target of 95%. The IQR and 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. Some Behavioral Health and Medical individual clinicians and business areas fell below the goal and were identified for corrective actions should they continue to score below the goal. These IQR/IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services. [redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
The factors and sources used in determining what OON services are subject to precertification, and in handling precertification requests, are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization
Benefit Classifications/Subclassification

- **Out-of-Network Outpatient All Other subclassification**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Description of NQTL: The Member Precertification List (MPL) is part of the certificate of coverage which is filed with each State department of insurance. 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. The analysis below is for Aetna's standard certificate of coverage.

Medical/Surgical (M/S) services NQTL applies to:	Mental Health and Substance Use Disorder (MH/SUD) services NQTL applies to:
Outpatient-All Other: • Advanced reproductive technology (ART) services • Complex imaging • Comprehensive infertility services • Cosmetic and reconstructive surgery • Gene-based, cellular and other innovative therapies (GCIT) • Injectables (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications) • Gender affirming treatment • Kidney dialysis • Knee surgery • Non-emergency transportation by airplane • Outpatient back surgery not performed in a physician's office • Private duty nursing services • Sleep studies • Wrist surgery	**Outpatient-All Other:** • Applied behavior analysis • Gender affirming treatment • Partial hospitalization treatment • Transcranial magnetic stimulation (TMS)

Certificate of Coverage language:

Medical necessity[and, precertification] requirements

Your plan pays for its share of the expense for **covered services** only if the general requirements are met. They are:

- The service is **medically necessary**
- [For in-network benefits, you get the service from a **network [provider]**]
- [You or your **[provider] precertifies** the service when required]

[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. **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.] 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**
- **Stays** in a **skilled nursing facility**]

[Outpatient –

- [ART services]

- Complex imaging
- [Comprehensive **infertility** services]
- 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**
- Non-emergency transportation by airplane
- Outpatient back **surgery** not performed in a **[physician's]** office
- [Obesity (bariatric) **surgery]**
- Partial hospitalization treatment – **mental health 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**.

Our clinical policy bulletins explain our policy for specific services and supplies. We use these bulletins and other resources to help guide individualized coverage decisions under our plans. You can find the bulletins and other information at [https://www.aetna.com/health-care-professionals/clinical-policy- bulletins.html]

Glossary:

Precertification, precertify

Pre-approval that you or your **[provider]** receives from us before you receive certain **covered services**. This may include a determination by us as to whether the service is **medically necessary** and eligible for coverage.

Schedule of Benefits language:

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 benefit reduction of [0%-50%] up to a maximum of [$100-$500] for each type of **covered occurrence.**
- **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**]

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.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes: Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors: *Factors used in designing the NQTL*
The factors used in designing the original Member Precertification List cannot be listed because the MPL has existed long before the MHPAEA regulations were issued and there was not an explicit list of factors or processes. Effective September 2023, the factors and process for adding or removing a service from the MPL have been formalized in the **Member Precertification List Policy and Procedure**. The factors are: <u>Adding a Service, Drug or Device to the MPL:</u> [redacted]

[redacted]

[redacted]

[redacted]

Removing a Service, Drug or Device from the MPL:

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources: *Processes, strategies and/or evidentiary standards used to design and apply the NQTL*
Process for Developing the MPL**:** The Policy and Plan Design Committee (PPDC), a group of clinicians, product managers, legal counsel, compliance leads, and other subject matter experts representing both MH/SUD and M/S expertise, is responsible for deciding whether to add or remove services from the MPL. See Appendix to the UM NQTLs for the PPDC composition. PPDC members and business partners may propose changes to the MPL. The PPDC considers the factors listed above and votes on whether to approve a change. Any 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. The process is comprehensively described in the **Aetna Member Precertification List (MPL) Policy & Procedure.** Evidentiary Standards for Developing the MPL: • Medicare rates • Internal analysis of administrative costs • Clinical guidelines and standards of practice Process and Standards for Performing Precertification: Aetna's processes for precertifying services that are on the MPL are designed in accordance with National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, and applicable state and federal law. In brief, precertification requests and supporting documentation are reviewed by clinical support staff who are not licensed health care providers. They can make coverage approvals that do not require clinical review, and 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 who are RNs, licensed behavioral health clinicians. If a licensed clinician is unable to approve coverage, the clinician refers the request to a Medical Director who is a physician or to a consulting psychiatrist/ psychologist/ board certified behavior analyst- doctoral (BCBA-D) for further review and action. Consulting psychiatrists/psychologists/BCBA-D use the available clinical

information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) The precertification determination is made and communicated to the provider/member according to the established timeframes for urgent or non-urgent requests. In some circumstances the treating provider may have a peer-to-peer consultation with a physician.

- [redacted]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

As Written: The same factors and sources, and the same Member Precertification List Policy and Procedure, apply to MH/SUD and M/S benefits in deciding which services to add to or remove from the Member Precertification list. The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling precertification requests for MH/SUD and M/S benefits. Thus, as written this NQTL is applied comparably, and not more stringently, to
MH/SUD benefits.

Plan/Issuer Response – In Operation:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

In Operation: The following measures are used to assess comparability and stringency:

Evaluation of determinations adding to or removing MH/SUD and M/S services from the MPL: Precertification is required for all inpatient admissions for both MH/SUD and M/S services. Precertification is not required for any MH/SUD or M/S Outpatient-Office Visits. As for Outpatient-All Other benefits, there are only 4 MH/SUD services in that classification subject to precertification compared to approximately 13 *categories* of M/S services. From this information it can be inferred that the factors and sources used to add or remove a service from the MPL are not being applied more stringently to MH/SUD services.

Denial Rates and turnaround times for OON MH/SUD and M/S precertifications: [redacted]

Out-of-Network Precertification Decisions	Inpatient M/S	Inpatient MH/SUD		Outpatient M/S	Outpatient MH/SUD
Total Decisions	[redacted]	[redacted]		[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]		[redacted]	[redacted]
Overall Percent Denied	[redacted]	[redacted]		[redacted]	[redacted]
Average Decision TAT (Days)	[redacted]	[redacted]		[redacted]	[redacted]

[redacted]

Internal Quality Reviews and Inter-Rater Reliability assessments: The IQR/IRR process described in [redacted] provides a way to evaluate whether utilization review of MH/SUD and M/S 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 the goal of 90%. Corrective action plans and appropriate monitoring are also established for business areas with a final score below the target of 95%. The IQR and 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. Some Behavioral Health and Medical individual clinicians and business areas fell below the goal and were identified for corrective actions should they continue to score below the goal. These IQR/IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services. [redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
The factors and sources used in determining what OON services are subject to precertification, and in handling precertification requests, are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Concurrent Review

Benefit Classification/Subclassification

- **In network Inpatient**
- **Out of network Inpatient**
- **In network Outpatient All Other Subclassification**
- **Out of network Outpatient All Other Subclassification**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Description of NQTL:
Concurrent review is performed by licensed healthcare professionals to review the medical necessity of a patient's care while in the hospital, 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.

Concurrent review is performed on all inpatient admissions that are subject to precertification and entail an ongoing course of treatment. (See the Prior Authorization NQTL Comparative Analysis for information about precertification.)

M/S services NQTL applies to:	MH/SUD services NQTL applies to:
All inpatient admissions that extend beyond the initial precertification: 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)	All inpatient admissions subject to precertification that entail an ongoing course of treatment: All inpatient admissions including residential treatment facilities

Certificate of Coverage language:

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 external 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.

If benefits are not paid within 30 days after proof of loss is received, the network provider is entitled to 9% interest. Interest will be calculated from the 30th day until the date the benefits are paid. However, interest less than $1 may not be paid.

Step 2:
Identify the factors used to determine that the NQTL will apply to mental health or substance abuse disorder and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes: Identification of any factors, evidentiary standards or sources, strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance abuse disorder benefits and medical or surgical benefits, are subject to the NQTL.

Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan Response:

Factors: *Factors used in designing the NQTL*
The factors used in determining what services are subject to precertification and, by extension, to concurrent review, are described in Aetna's Prior Authorization NQTL Comparative Analysis. In addition, for Outpatient-All Other services, the inability of a service to be managed through quantitative treatment limits is a factor in whether it is subject to concurrent review. The factors used in determining how concurrent review is performed are: • [redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources: *Processes, strategies and/or evidentiary standards used to design and apply the NQTL*
The processes and evidentiary standards used in determining what services are subject to precertification and, therefore, to concurrent review, are described in Aetna's Prior Authorization NQTL Comparative Analysis. Evidentiary Standards for Performing Concurrent Review: Aetna's concurrent review processes are designed in accordance with National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, and applicable state and federal law. Strategy for Performing Concurrent Review: For both MH/SUD and M/S 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. They rely upon their training and experience, informed by the member's medical history, clinician progress notes and discharge plans, to assess "severity" and "complexity" (as those terms are used within Aetna's National Clinical Services policies and procedures and clinical guidelines). Process for Performing Concurrent Review: Concurrent review is initiated before the authorized coverage period under the initial precertification or previous concurrent review expires. Updated information about the patient's condition, progress and treatment/discharge plan is obtained from the provider. Concurrent reviews are performed by licensed clinicians who are RNs, licensed behavioral health clinicians. The licensed clinician may approve coverage for additional units of care or, if unable to approve coverage, will refer the case to a Medical Director who

is a physician or to a consultant psychiatrist/ psychologist/ board certified behavior analyst-doctoral (BCBA-D) for further review and action. Consultant psychiatrists/ psychologists/ BCBA-Ds use the available clinical information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) The concurrent review determination is made and communicated to the provider/member according to the established timeframes for urgent or non-urgent requests. In some circumstances the treating provider may have a peer-to-peer consultation with a physician.

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance abuse disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance abuse disorderand medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in the administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance abuse disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan Response – As Written:

Comparability and Stringency Analysis: *Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation*
As Written: The same factors and sources apply to MH/SUD and M/S benefits in deciding which services are subject to precertification and, by extension, to concurrent review. The same factors and sources,

and the same National Clinical Services Policies and Procedures, apply to handling concurrent review requests for MH/SUD and M/S benefits. Thus, as written this NQTL is applied comparably, and not more stringently, to MH/SUD benefits.

Plan Response – In Operation:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

In Operation: The following measures are used to assess comparability and stringency:

Denial Rates and turnaround times for INN and OON MH/SUD and M/S concurrent reviews: [redacted]

Concurrent Review Decisions	Inpatient M/S	Inpatient MH/SUD	Outpatient MH/SUD: PHP
Total Decisions	[redacted]	[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]	[redacted]
Overall Percent Denied	[redacted]	[redacted]	[redacted]
Average Decision TAT (Days)	[redacted]	[redacted]	[redacted]

[redacted]

Aetna does not perform concurrent review on outpatient M/S services because outpatient M/S services involving ongoing courses of treatment are subject to quantitative limitations that do not apply to outpatient MH/SUD services. For example, the Plan places treatment limits on hyperbaric oxygen therapy and private duty nursing. Since Aetna imposes quantitative limitations on these M/S services, the application of concurrent review is not needed. As an aside, if the type of M/S service doesn't involve an ongoing course of treatment, the service is organically limited by its nature (e.g., a surgery, a device), and thus limited to the extent medically necessary. Procedurally, M/S services subject to precertification would ordinarily be subjected to concurrent review if there was a request for continuing services, but for the more stringent application of quantitative limitations. As a result, these services must be reviewed again for medical necessity in the precertification process (as opposed to concurrent review).
Alternatively, the MH/SUD services involving an ongoing course of treatment on the NPL are not subject to strict visit limits. Aetna does not place quantity limitations on MH/SUD benefits because of legal prohibitions in doing so. Aetna's application of concurrent review to MH/SUD services is MHPAEA- compliant because M/S services subject to concurrent review have a greater restriction imposed (e.g.,

visit / service limits), than what is applied to MH/SUD services in the same benefit classification. If the M/S outpatient services were not regulated by the limits imposed, they would be subject to concurrent review.

Internal Quality Reviews and Inter-Rater Reliability assessments: The IQR/IRR process described in [redacted] provides a way to evaluate whether utilization review of MH/SUD and M/S 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 the goal of 90%. Corrective action plans and appropriate monitoring are also established for business areas with a final score below the target of 95%. The IQR and 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. Some Behavioral Health and Medical individual clinicians and business areas fell below the goal and were identified for corrective actions should they continue to score below the goal. These IQR/IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services. [redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer

is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
The factors and sources used in determining what services are subject to precertification (and by extension, to concurrent review), and in performing concurrent reviews, are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents (submitted with production as separate exhibits)
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Retrospective Review

Benefit Classification/Subclassification

- **In-network Inpatient**
- **Out-of-network Inpatient**
- **In-network Outpatient All Other Subclassification**
- **Out-of-network Outpatient All Other Subclassification**
- **Emergency**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan Response:
Description of NQTL:
Retrospective review is a utilization review service performed by licensed healthcare professionals to determine coverage after treatment has been given. The intent is to determine medical necessity, appropriateness of treatment, and benefits and eligibility.

For OON services, Aetna performs retrospective review on OON Inpatient services that were not precertified and OON Outpatient All-Other services that are on the member precertification list and were not precertified. For INN services, Aetna performs retrospective review in the following limited circumstances: when an INN psychiatric hospital or other MH/SUD or M/S facility that is not a Hospital or Children's Hospital failed to precertify or give timely notice of

inpatient admission; when required by state law or Aetna's contract with a facility; when provider precertification requirements are waived due to a state or federal disaster declaration; or 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 on M/S and MH/SUD services where the diagnosis code signifies a condition that potentially was not an "emergency" under the federal "prudent layperson" standard.

M/S services NQTL applies to:	**MH/SUD services NQTL applies to:**
All OON M/S inpatient services, and all outpatient-all other services on the Member Precertification List, that were not precertified. INN inpatient services when provided by a facility (other than a hospital or children's hospital) that failed to precertify or give timely notice of admission. "Emergency" M/S services on the Non-Emergent ER Diagnosis List	All OON MH/SUD inpatient services, and outpatient-all other services on the Member Precertification List, that were not precertified. INN inpatient services when provided by a psychiatric hospital or facility (other than a hospital or children's hospital) that failed to precertify or give timely notice of admission. "Emergency" MH/SUD services on the Non- Emergent ER Diagnosis List

There is no form language related to this NQTL.

Step 2:
Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan Response:

Factors: *Factors used in designing the NQTL*
The factors used in determining what services are subject to retrospective review are: • [redacted] [redacted] factors used in determining how retrospective review is performed are: • [redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan Response:

Sources: *Processes, strategies and/or evidentiary standards used to design and apply the NQTL*
Some of the processes and evidentiary standards used in determining what services are subject to retrospective review are described in Aetna's Prior Authorization NQTL Comparative Analysis. Additionally, Aetna reviews its contracts with participating facility providers and monitors state and federal laws and disaster declarations to determine when the standard obligation for the provider to give timely notice of an admission must be waived; when the obligation to give timely notice of an admission is waived, then Aetna will perform retrospective review instead of imposing a payment penalty on the participating provider. Regarding the list of non-emergent diagnosis codes that trigger a retrospective review of "emergency" services, that list is maintained by Aetna's Payment Policy and Coding Committee (PPCC). The composition of the Committee is described in the Appendix. The Medical Directors on the PPCC review ICD10 and DSM-V coding descriptions and apply their clinical training, experience and judgment to assess whether the symptoms would typically cause a "prudent layperson" (as that term is defined in federal law) to believe emergency care was needed. Evidentiary Standards for Performing Retrospective Review: The evidentiary standards/sources for Aetna's retrospective review processes are National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, applicable state and federal law. Strategy for Performing Retrospective Review: For both MH/SUD and M/S services, the guiding strategy behind retrospective review relies upon the clinical reviewers' exercise of their clinical judgment based on their training and experience, guided by clinical criteria and informed by the member's medical history, to determine whether to approve coverage for care already provided.

Process for Performing Retrospective Review: Retrospective review is performed after services have already been provided. It is done by licensed clinicians who are RNs, licensed behavioral health clinicians. The licensed clinician may approve coverage or, if unable to approve coverage, will refer the case to a Medical Director who is a physician or to a consultant psychiatrist/ psychologist/ board certified behavior analyst-doctoral (BCBA-D) for further review and action. Consultant psychiatrists/ psychologists/ BCBA-Ds use the available clinical information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) For retrospective reviews of non-emergent diagnosis codes, a Medical Director reviews the available clinical information and applies his or her clinical training, experience and judgment to evaluate whether a "prudent layperson" (as that term is used under applicable law) would have believed emergency care was required. The retrospective review determination is made and communicated to the provider/member according to the established timeframes. In some circumstances the treating provider may have a peer-to-peer consultation with a physician.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan Response – As Written:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

As Written:
The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling retrospective review requests for MH/SUD and M/S benefits. Regarding "emergency" services that are subject to retrospective review, of the 1589 diagnosis codes that trigger retrospective review, only 80 (5%) are for MH/SUD conditions. Thus, as written this NQTL is applied comparably, and not more stringently, to MH/SUD benefits.

Plan Response – In Operation:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

The following measures are used to assess comparability and stringency:

Denial Rates for INN and OON MH/SUD and M/S retrospective reviews: [redacted]

INPATIENT	M/S	MH/SUD
Total Decisions	[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]
Percent Denied	[redacted]	[redacted]

OUTPATIENT	M/S	MH/SUD
Total Decisions	[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]
Percent Denied	[redacted]	[redacted]

[redacted]

[redacted]

Internal Quality Reviews and Inter-Rater Reliability assessments: The IQR/IRR process described in [redacted] provides a way to evaluate whether utilization review of MH/SUD and M/S 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 the goal of 90%. Corrective action plans and appropriate monitoring are also established for business areas with a final score below the target of 95%. The IQR and 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. Some Behavioral Health and Medical individual clinicians and business areas fell below the goal and were identified for corrective actions should they continue to score below the goal. These IQR/IRR reports show that utilization review is performed comparably, and not more stringently, for MH/SUD services. [redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include: (Q

2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan Findings and Basis for Conclusion:

Summary of Conclusions:
The factors and sources used in determining what services are subject to retrospective review, and in performing retrospective reviews, are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents (submitted with production as separate exhibits)
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Medical Necessary Criteria Benefit

Classification/Subclassification

- **In-network Inpatient**
- **Out-of-network Inpatient**
- **In-network Outpatient**
  Office Visit
  Subclassification
- **Out-of-network Outpatient**
  Office Visit
  Subclassification
- **In-network Outpatient All**
  Other Subclassification
- **Out-of-network Outpatient All Other**
  Subclassification
- **Emergency**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan Response:

Plan Terms and/or Description of NQTL:

According to the standard language of Aetna's benefit plans, "medically necessary" or "medical necessity" means:

"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 and 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"

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

- 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-abaguidelines.html)
- Level of Care Utilization System for Psychiatric and Addictive Services (LOCUS) (www.aetna.com/health- care-professionals/patient-careprograms/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)

Fully insured plans in a state that mandates a different definition of medical necessity are administered in accordance with the state's requirements.

M/S services NQTL applies to:	MH/SUD services NQTL applies to:
All inpatient, outpatient, and emergency care services	All inpatient, outpatient, and emergency care services

Certificate of Coverage language:

Medical necessity [and precertification requirements]

Your plan pays for its share of the expense for **covered services** only if the general requirements are met. They are:

- The service is **medically necessary**
- For in-network benefits, you get the service from a **network provider**
- You or your **provider precertifies** the service when required

Medically necessary, medical necessity

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**.

Important note:
We cover **medically necessary**, sex-specific **covered services** regardless of identified gender.

Glossary

Medically necessary, medical necessity

Health care services that we determine a **provider**, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an **illness, injury**, disease or its symptoms, and that we determine are:

- In accordance with generally accepted standards of medical practice
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's

illness, injury or disease

- Not primarily for the convenience of the patient, **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 that patient's illness, injury or disease

Generally accepted standards of medical practice means:

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

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan Response:

Factors: *Factors used in designing the NQTL*
Aetna's Clinical Policy Council (CPC) follows a standard process to develop and/or approve medical necessity criteria for MH/SUD and M/S services. As detailed in the Aetna Clinical Policy Council Charter, the factors the CPC considers are: [redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan Response:

Sources:
Processes, strategies and/or evidentiary standards used to design and apply the NQTL

Strategy: Medical necessity determinations rely upon the clinical reviewers' exercise of their clinical judgment based on their training and experience, guided by clinical criteria adopted by the Clinical Policy Council, and informed by the member's clinical presentation, to determine whether to authorize coverage.

Sources and Evidentiary Standards:

- Evidence in the peer-reviewed published medical literature
- Evidence-based consensus statements
- Expert opinions of healthcare providers
- Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies
- Technology assessments and structured evidence reviews
- Clinical training, experience and judgment of Aetna's clinical reviewers

Process:
Aetna's Chief Medical Officer (CMO) and by delegation, the Vice President for Clinical Policy, is charged with whether medical services, drugs and devices are considered experimental, cosmetic, or medically necessary. The Aetna Clinical Policy Council provides guidance and advice to the CMO or designee on specific clinical topics under review for coverage (see Aetna Clinical Policy Council Charter). The voting members of the CPC are pharmacists and medical directors from the Medical Policy and Operations (MPO) department, National Accounts department, Behavioral Health department, Clinical Pharmacy department and regional Patient Management units (see the Appendix to UM NQTLs for the complete Aetna Clinical Policy Council composition). The CPC applies the factors, sources and evidentiary standards identified above to develop (in the case of Aetna® Clinical Policy Bulletins) or approve (in the case of clinical guidelines published by third parties) evidence-based guidelines that are used by Aetna's clinicians to evaluate the medical necessity of a service, drug or device. The CPC has approved the Clinical Policy Bulletins to be used by Aetna's clinicians in making medical necessity determinations:

Aetna® Clinical Policy Bulletins (CPBs) (MH/SUD and M/S)
Aetna CPBs are developed and approved by the CPC based on the factors, sources and evidentiary standards listed above. Both new and revised CPBs undergo a comprehensive review process entailing review by the CPC and external practicing clinicians, and approval by Aetna's Chief Medical Officer or designee. In developing a CPB, for each technology selected for evaluation the CPC conducts a comprehensive search of the peer-reviewed published medical literature indexed in the National Library of Medicine PubMed Database, assesses the regulatory status of the technology, reviews relevant evidence- based clinical practice guidelines and related documents indexed in the Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse Database, and reviews relevant technology assessments indexed in the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Database. The opinions of relevant experts are obtained where that would be informative. Once approved, new or revised CPBs are published on Aetna's public websites within 60 days. CPBs are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other information warrants more frequent review. 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 and investigational status or medical necessity of the technology. If the CPC determines that new evidence or other information has emerged to warrant consideration of a change in our clinical policy, a revised CPB is prepared. If no new evidence has emerged that would warrant a change in position, the CPB may be updated with additional supporting background information and references. Each revised and updated CPB is submitted to the CPC for review and approval.

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. The decision to use MCG was made in 2002.

ASAM (MH/SUD)
Aetna uses the criteria published by the American Society of Addiction Medicine (ASAM), 3rd Edition, 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. Aetna has been using ASAM criteria for over 20 years. Some states, notably New York and New Jersey, require state-specific SUD level of care criteria. In those states, Aetna uses the criteria required by law.

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 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.

The decision to adopt LOCUS and CALOCUS was made in 2021 by Aetna's Chief Psychiatric Officer, in consultation with Behavioral Health (BH) Senior Medical Director (MD) and other members of the BH Clinical Operations leadership team, after consideration of other tools. Aetna's National Quality Advisory Committee (NQAC - a committee that includes external members and participating providers) and National Quality Oversight Committee (NQOC) approved the decision.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan Response – As Written:

Comparability and Stringency Analysis: *Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more* *stringent than, those for M/S, as written and in operation*
As Written: Aetna applies the same strategy, Certificate of Coverage definition of "medical necessity", and factors/sources/process to determine medical necessity for both MH/SUD and M/S services. The Aetna Clinical Policy Bulletins and third-party clinical guidelines used by clinicians to make MH/SUD and M/S medical necessity determinations are developed and adopted by the same Clinical Policy Council pursuant to its written charter. This satisfies the as-written comparability and stringency tests.

Plan Response – In Operation:

Comparability and Stringency Analysis:

Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

In Operation: Reviewing denial rates for precertification, concurrent review and retrospective review decisions provides a way to compare how Aetna determines medical necessity for MH/SUD and M/S services in operation.

Denial Rates for MH/SUD and M/S medical necessity reviews: [redacted]

Medical Necessity Review Decisions	**Inpatient M/S**	**Inpatient MH/SUD**		**Outpatient M/S**	**Outpatient MH/SUD**
Total Decisions	[redacted]	[redacted]		[redacted]	[redacted]
Denied Decisions	[redacted]	[redacted]		[redacted]	[redacted]
Overall Percent Denied	[redacted]	[redacted]		[redacted]	[redacted]

[redacted]

Step 5:
The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan Findings and Basis for Conclusion:

Summary of Conclusions:
The factors and sources used to determine medical necessity are comparable, and not more stringent, for MH/SUD benefits both in writing and in operation.
Referenced Policies and Documents


Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Experimental/Investigational
Benefits
Classification/Subclassification

- **In-network inpatient**
- **Out-of-network inpatient**
- **In-network outpatient office visit subclassification**
- **Out-of-network outpatient office visit subclassification**
- **In-network outpatient all other subclassification**
- **Out-of-network outpatient all other subclassification**
- **Emergency**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Description of the NQTL:
The NQTL of Experimental/Investigational is a limitation on the scope or duration of treatment by determining a threshold for coverage of a particular service or supply to ensure they are clinically appropriate for the treatment of conditions warranting their use. The Aetna Chief Medical Officer (CMO), and by delegation, the Vice President, Aetna Quality Management and Clinical Policy Development, is charged with determining whether medical technologies are considered experimental or investigational as that term is defined under Aetna's medical benefit plans. The Aetna Clinical Policy Council (the Council) provides guidance and advice to Aetna's CMO, or designee, on specific clinical topics under review for coverage under Aetna medical benefit plans.

Certificate of Coverage language

Glossary:

Experimental or investigational

Drugs, treatments or tests not yet accepted by [physicians] or by insurance plans as standard treatment. They may not be proven as effective or safe for most people.

A drug, device, procedure, or treatment is experimental or investigational if:

- 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.
- The needed approval by the FDA has not been given for marketing.
- A national medical or dental society or regulatory agency has stated in writing that it is experimental or investigational or suitable mainly for research purposes.
- It is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial. These terms have the meanings given by regulations and other official actions and publications of the FDA and Department of Health and Human Services.
- Written protocols or a written consent form used by a facility [provider] state that it is experimental or investigational.

Provider Manual, page 17

https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/office_manual_hcp.pdf

Medical clinical policy bulletins

Aetna Clinical Policy Bulletins (CPBs) are internally developed policies that we use as a guide for determining health care coverage for our members. Our CPBs are written on selected clinical issues, especially addressing new medical technologies such as devices, drugs, procedures and techniques. CPBs apply to all Aetna medical benefit plans and are used in conjunction with the terms of the member's benefit plan and other Aetna- recognized criteria to determine health care coverage for our members. Our benefits plans generally exclude from coverage medical technologies that are considered experimental and investigational, cosmetic and/or not medically necessary.

CPBs are continually reviewed and updated to reflect current information.

We review new medical technologies and new technology applications regularly. We determine whether and how such technologies will be considered medically necessary and/or not experimental/investigational under our benefits plans.

Our process of assessing technologies begins with a complete review of the peer-reviewed medical literature and other recognized references concerning the safety and effectiveness of the technology. This evaluation involves analyzing the results of studies published in peer-reviewed medical journals.

We consider the position statements and clinical practice guidelines of medical associations and government agencies, including the Agency for Healthcare Research and Quality (AHRQ). When applicable, we consider the regulatory status of a drug or device, including:

- Review by the U.S. Food and Drug Administration (FDA)
- Centers for Medicare & Medicaid Services (CMS) coverage policies

We develop our CPBs from a review of relevant information regarding a particular technology. CPBs are published on our website for public reference.

Medical/Surgical benefits subject to the NQTL	MH/SUD benefits subject to the NQTL
Aetna develops and maintains more than 1,000 Clinical Policy Bulletins which detail the services and procedures Aetna considers experimental/investigational or medically necessary. Most of these CPB's apply to medical/surgical services. The complete list is available at https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/medical- clinical-policy-bulletins.html.	Aetna develops and maintains more than 1,000 Clinical Policy Bulletins which detail the services and procedures Aetna considers experimental/investigational or medically necessary. Most of these CPB's apply to medical/surgical services. The complete list is available at https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/medical- clinical-policy-bulletins.html.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors
N/A. Plans/issuers do not need to complete this step for this NQTL.

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes: To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.
The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:
Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Evidentiary Standards

A drug, device, procedure, or treatment is experimental or investigational if:

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.

- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. 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 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.

The needed approval by the FDA has not been given for marketing.

- This criterion applies to drugs, biological products, devices and any other 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.
- Any approval that is granted as an interim step in the U.S. Food and Drug Administration's or any other federal governmental body's regulatory process is not sufficient.
- The indications for which the technology is approved need not be the same as those which Aetna's Clinical Policy Council is evaluating.

A national medical or dental society or regulatory agency has stated in writing that it is experimental or investigational or suitable mainly for research purposes.

- 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.

It is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial. These terms have the meanings given by regulations and other official actions and publications of the FDA and Department of Health and Human Services. The below definitions are from fda.gov.

- Phase I trials: Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.
- Phase II trials: The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- Phase III trials: The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

Sources

- Peer-reviewed published medical literature
- Regulatory status of the technology including FDA and other regulatory bodies
- Evidence-based clinical practice guidelines and related documents
- 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.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

As written

Aetna's analysis of the "as written" strategies in place to determine what services, drugs, and devices are considered experimental or investigational 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. Specifically, Aetna applies the following internal written policies to determine what treatments are considered experimental or investigational:

- Clinical Policy Council Charter
- Process for Review and Approval of Aetna Clinical Policy Bulletins

Together, these documents represent the "written" strategies and processes Aetna employs to review services, drugs, and treatments 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***; the same Clinical Policy Council reviews all medical technologies, using the same procedure described below.

More specifically, the **Clinical Policy Council Charter** defines the Council's membership structure, function and specific tasks, meeting frequency and agenda, and the criteria for determining medical necessity of the medical technologies under consideration. Meetings are held approximately two times per month, and the Chief Medical Officer or their designee will approve the agenda. The Council membership includes medical-level practitioners representing a wide range of board specialties in both the areas of medical/surgical and mental health/substance use disorders. The Council also includes non-voting members from operations, dental, product development, legal, and other departments. The meeting structure is designed to gather input from various departments and include additional subject matter experts as needed, based on the agenda topics.

The Clinical Policy Council uses the factors and evidentiary standards described above to determine whether a medical technology is medically necessary and established. These are listed in the Charter and apply equally to M/S and MH/SUD. The CPC membership, including each member's role at Aetna and credentials, is included as an appendix at the end of this report.

Additionally, the **Process for Review and Approval of Aetna Clinical Policy Bulletins** defines the process the Clinical Policy Council uses to review new medical technologies for coverage, as well as the ongoing review and maintenance of Aetna's Clinical Policy Bulletins.

Aetna's Clinical Policy Bulletins are posted publicly on Aetna's website at https://www.aetna.com/health-care-professionals/clinical-policy-bulletins/medical-clinical-policy-bulletins.html. The "What's new" tab highlights additions, revisions, updates, and deletions and can be sorted by date.

As an example, CPB 0469, Transcranial Magnetic Stimulation and Cranial Electrical Stimulation was revised on 07/16/2024. The "Last Review" link summarizes the changes:
This CPB has been revised to: (i) change age criterion from 18 years or older to 15 years or older for coverage of transcranial magnetic stimulation (TMS); (ii) update Seroquel XR dosage in the table of antidepressants in the Appendix; and (iii) state that TMS is considered experimental, investigational, or unproven for the treatment of executive function deficits, gambling disorder, and phantom limb pain.

This CPB has been revised to state that accelerated, repetitive, MRI-guided theta-burst stimulation, also known as the Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) is considered experimental, investigational, or unproven for the treatment of depression and other psychiatric/neurologic disorders.

The change in the minimum eligible age is based on the May 2024 FDA approval for NeuroStar TMS therapy for patients aged 15 and older with depression. The CPB includes a separate discussion of recent studies testing TMS for executive function deficits, gambling disorder, and phantom limb pain. For executive function, the researchers concluded that TMS was feasible, but preliminary results were unsupportive of its effectiveness and stated that a future randomized clinical trial with a larger sample size with stratification of variables was required. The studies for gambling disorder similarly concluded that preliminary results were promising and made recommendations for additional future clinical trials. The authors of the study for phantom limb pain admitted the study had several drawbacks and the results of the study did not allow for conclusions regarding the long-term effects of rTMS. Therefore, TMS for these conditions is currently considered experimental and investigational.

For comparison, the CPC reviewed M/S CPB 0352, Tumor Markers, and published a revision on 10/03/2023: This CPB has been revised to state that InVisionFirst-Lung is considered medically necessary for persons with non-small cell lung cancer who are not medically fit for invasive sampling, or there is insufficient tissue for molecular analysis and follow-up tissue-based analysis will be done if an oncogenic driver is not identified. This CPB has been revised to state that the following tests are considered experimental and investigational: (i) AMBLor Melanoma Prognostic Test, (ii) Grail Galleri Test, (iii) OncobiotaLUNG, (iv) Pharmaco-oncologic Algorithmic Treatment Ranking Service, and (v) Strata Select. This CPB is revised to state that repeating a solid organ or hematological malignancy genomic sequencing panel within 60 days of prior panel testing for the same indication is considered not medically necessary. This CPB is revised to state that CA19-9 is considered medically necessary for persons with evidence of hepatobiliary obstruction or abnormality on abdominal imaging.

This CPB includes a separate discussion on the evidence in peer-reviewed literature for each test that is eligible for coverage or experimental/investigational. The InVisionFirst-Lung liquid biopsy assay was recently FDA approved, and the CPB includes a description of the analytical validation study method and results. This assay is eligible for coverage because of the FDA approval as well as the study's demonstration of high sensitivity and specificity in detection genomic alterations. The CPB includes details of each test that is considered experimental and investigational with an explanation of why. The AMBLor Melanoma Prognostic Test does not have sufficient evidence in the peer-reviewed literature to support its sensitivity or specificity. AMBLor is a test in development and is not yet FDA approved. Similarly, the Grail Galleri Test is not yet FDA approved, and there is insufficient evidence in the peer-reviewed literature to support the sensitivity or specificity of this test. For OncobiotaLUNG, the FDA granted a breakthrough device designation, but because there is no FDA approval and there is insufficient evidence in the peer-reviewed literature to support the sensitivity or specificity of this test, Aetna deems it experimental and investigational.

Both the M/S and MH/SUD Clinical Policy Bulletins include medically necessary and experimental indications for the services. Both CPBs include a review of and discussion of the relevant literature, including an analysis of the clinical studies. Both are reviewed no less than annually. As there are new studies, the experimental/investigational status medical tests, treatments, and devices may change.

Plan/Issuer Response – In Operation:

In Operation

[redacted]

	Medical/Surgical	MH/SUD
Count of claims denied as E&I	[redacted]	[redacted]
Percentage of claims denied as E&I	[redacted]	[redacted]

[redacted]

	Medical/Surgical	MH/SUD
Count of precertification requests denied as E&I	[redacted]	[redacted]
Percentage of precertification requests denied as E&I	[redacted]	[redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Conclusion

In conclusion, Aetna has demonstrated that both, as written and in operation, the processes, strategies, and evidentiary standards used to determine which MH/SUD services, supplies, and medical technologies are considered experimental/investigational under some or all circumstances are comparable to and applied no more stringently than the processes, strategies and evidentiary standards used to determine which M/S services, supplies, and medical technologies are considered experimental/investigational under some or all circumstances. The same definition of experimental/investigational within the Certificate of Coverage applies to both MH/SUD and M/S services.

In addition, Aetna uses the processes and standards as written in the Clinical Policy Council Charter and Process for Review and Approval of Aetna Clinical Policy Bulletins comparably for MH/SUD and M/S medical technology reviews and no more stringently for MH/SUD medical technology reviews than M/S reviews. These internal written policies require Aetna's Clinical Policy Council to consider and cite peer-reviewed published medical literature and evidence-based clinical practice guidelines, as well as the regulatory status of the technology, such as FDA approvals. These evidentiary standards apply equally to MH/SUD and M/S medical technology reviews.

The Clinical Policy Bulletin development and review process requires the evaluation and citation of these evidentiary standards in the public CPBs, which applies equally to M/S and MH/SUD. The CPB review process requires CPBs and the associated medical literature to be reviewed no less than annually, and also includes a process for updating CPBs as new medical technologies are approved. This is the case for the TMS example discussed in Step 4, where the FDA cleared NeuroStar TMS for adolescents aged 15-21, prompting an update for this coverage to the CPB.

Through the literature review process, for both M/S and MH/SUD procedures and technologies, Aetna's Clinical Policy Council evaluates the peer-reviewed literature, ensuring that the outcome data is based on well-designed and well-conducted investigations, and that there is evidence or a convincing argument based on medical facts that the technology affects health outcomes. For both M/S and MH/SUD technologies, products, and devices that require FDA approval for marketing, Aetna will consider the technology experimental/investigational if there is no FDA approval. Any approval granted as an interim step (such as breakthrough device designation) is not sufficient, as shown in the Tumor Markers CPB and the determination for the OncobiotaLUNG assay.

Moreover, a review of the in-operation data demonstrates parity compliance. Experimental/investigational denials comprise less than 0.25% of claims overall, accounting for M/S and MH/SUD claims, and there were zero experimental/investigational denials for MH/SUD claims or precertification requests. This shows that in-operation, the experimental/investigational NQTL is applied to MH/SUD no more stringently than to M/S.

In conclusion, a review of the internal policies, procedures, and committee charters demonstrates that the determination of what MH/SUD services may be experimental/investigational is applied comparably to M/S services, and not more stringently than M/S services. This is supported by the in-operation data review. Consequently, Aetna concludes that the experimental/investigational NQTL was applied comparably to and no more stringently to MH/SUD benefits than M/S benefits.

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Outlier Review/Management Benefits

Classification/Subclassification

- **In-Network Outpatient-Office**
- **In-Network Outpatient-All Other**
- **In-Network Inpatient**
- **Out of Network Inpatient**
- **Out-of-Network Outpatient-Office**
- **Out-of-Network Outpatient-All Other**
- **Emergency**

T

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Description of the NQTL: Respectfully, Aetna disagrees that Outlier Review / Management, which is a component of industry standard fraud, waste, and abuse programs, **is an** NQTL because it does not limit the scope or duration of a member's treatment as contemplated by MHPAEA or its implementing regulations. Furthermore, Outlier Review / Management 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. As recently as the 2023 release of

proposed amendments and new regulations under MHPAEA, the issuing federal agencies identify methods to detect and handle fraud, waste, and abuse as ***exceptions*** to requirements applicable to NQTLs because the agencies are of the view that such limitations are premised on standards that generally provide an independent and less suspect basis for determining access to mental health and substance use disorder treatment. Notably, Aetna has not had to consider or otherwise analyze Outlier Review / Management through any federal Department of Labor audits or inquiries, despite having produced full listings of NQTL comparative analyses to regulators.

However, subject to and without waiving the foregoing objection, Aetna provides this submission as requested. For the purpose of this response, Aetna defines outlier review/management as the process by which 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.

In addition to referrals from members, Aetna staff, and state or federal agencies, the following data mining rules are 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. Therefore, ***all services*** that correspond to possible benefits are subject to Outlier Review / Management. 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. This list is subject to naturally change based on the factors and standards discussed more fully in later steps below.

Medical/Surgical	**MH/SUD**
• Genomics FWA Model • Massage • Allergy Self-Injecting Members • Ansar (Autonomic Nervous System Testing) • Extremity U/S Complete - Other than Podiatrist • Inclusive in Primary PX • Prolonged Services • Unlisted Misc. Codes • Unlisted Lab • Active Cold Compression Devices • Emergency Add-on • Unlisted Evaluation and Management(E&M) • Unlisted Ophth • High Level Home Visits • Oral Brush Biopsy • Colon Cleansing • Esophagogastroduodenoscopy • IOM • DME Network Analysis • Lab Codes billed > 20 Units • Convenience Medical Kits	• High frequency Evaluation and Management (E/M) billed by Psychiatrists • Recovery Treatment Facility/Substance Abuse Facility stay with outpatient services billed • Patient Brokering • Consecutive Partial Hospitalization/Intensive Outpatient Program for members out of state • QEEG, Brain Mapping and Neurofeedback

• Allergy Svcs by Non-Allergy Providers • Functional/Regenerative Medicine • Claim Volume Spike • Suspect Provider Demographics • Genetic Testing • UV Light Home Services Not Rendered • Lactation Consultants Double Bill Mom and Baby • Implantable Neurostimulator • High Risk Telehealth • COVID Drive Through • I/E Nerve Blocks and Treatments • Consecutive COVID Testing • MODEL: SCOUT • MODEL: High Risk Non-Par Providers • High claim counts per Member for POS office and clinic • HIV Spike Report • Par Providers Billing as Non-Participating • Out of Scope Billing Chiropractic Services • Plan Sponsor Overutilization • Direct Member Reimbursement (DMR) • At Home COVID Test Kits • Providers Billing High % of Compromised Members • Multiple Providers at Common Address Report (DME / LAB) • DBAR Preclusion Lists	

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors:

Factors used in designing the NQTL *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.*
[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:
To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.
The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:
Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Factors and Evidentiary Standards

[redacted]

- Billing for services not rendered means fabricating an entire claim or padding an otherwise legitimate claim with charges for services that did not take place.

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.

[redacted]

- "Upcoding" is billing for more expensive services than what was actually performed.
- "Unbundling" is billing for each step of a procedure as if they are separate procedures.

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.

Background: HIPAA required the Secretary of the Department of Health and Human Services (HHS) to adopt standards for coding systems that are used for reporting health care transactions. Thus, regulations were published in the Federal Register on August 17, 2000 (65 FR 50312), to implement standardized coding systems under HIPAA.

Sources and Evidentiary Standards:

- **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.

[redacted]

- 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.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

As written
All written materials used in establishing and conducting outlier review/management 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). This plan applies equally to both M/S and MH/SUD.

Plan/Issuer Response – In Operation:

In operation

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.

[redacted]

	Medical/Surgical	MH/SUD
Count of cases opened	[redacted]	[redacted]
Percentage of cases	[redacted]	[redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

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.

The factors are the same for both M/S and MH/SUD.

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 outlier review, as set forth above 5 MH/SUD benefit patterns were subject to outlier review, as compared to 45 categories of M/S benefit patterns subjected to outlier review. This demonstrates that this NQTL is applied to MH/SUD providers similarly to, and not more stringently than, M/S providers.

As written, Aetna uses the same written SIU Anti-Fraud Plan for both M/S and MH/SUD investigations. 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 Illinois during the reporting period shows that there were fewer cases for MH/SUD providers than for M/S providers. This indicates that outlier review is applied no more stringently to MH/SUD providers and claims than to M/S providers and claims.

Accordingly, Aetna concludes that outlier review and management for MH/SUD is applied similarly to and not more stringently than M/S claims and providers.

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Reimbursement – Participating Provider (Professionals) Benefit

Classifications/Subclassifications

- **In-network Inpatient**
- **In-network outpatient office visit subclassification**
- **In-network outpatient all other subclassification**
- **Emergency**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Plan Terms and/or Description of NQTL:

This NQTL is implemented by the plan's definition of Negotiated Charge, which 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).

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

Certificate of Coverage language:

[Negotiated charge

[For health coverage:

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.]

*[For **prescription** drug services:*

When you get a **prescription** drug, we have agreed to this amount for the **prescription** or paid this amount to the network pharmacy or third party vendor that provided it. The **negotiated charge** may include a rebate, additional service or risk charges and administrative fees. It may include additional amounts paid to or received from third parties under price guarantees.]]

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors:
Factors used in designing the NQTL

The following factors are used to establish the Aetna Market Fee Schedule ("AMFS"), which is the preferred fee schedule for MH/SUD and M/S network providers. AMFS rates are established at the market level by the Medical and Behavioral Health (BH) network teams in collaboration with Aetna's Medical Economics Unit (MEU). When a provider does not accept the AMFS, the AMFS is used as a starting point for contract negotiations.

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources:
Processes, strategies and/or evidentiary standards used to design and apply the NQTL

Strategy: Achieve 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 and drive membership growth.

Process:

1. [redacted]

[redacted]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits. The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written/In Operation:

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

There are two main steps for setting network provider reimbursement, which are the same for MH/SUD and M/S services: (1) developing and refreshing the AMFS rates which are the baseline for contracting with providers; and (2) contracting with providers. Below is the comparability and stringency analysis for each step.

(1) In developing and refreshing the AMFS rates, the Plan uses comparable factors, strategies, processes and evidentiary standards for MH/SUD and M/S services, both as written and in operation. There is a difference in the process for setting the rates for MH/SUD services that can also be billed by M/S providers, but this is more favorable for MH/SUD services – see [redacted] the codes that are shared by MH/SUD and M/S office based providers, showing no AMFS MH/SUD provider rates are lower, than the rates for M/S providers. For example, the rates for office-based MH/SUD physicians are higher than for office-based M/S physicians for the four most frequently billed shared codes, as shown by the chart below. The shared codes are evaluation and management services and can be billed by both M/S and MH/SUD physicians. Aetna's comparability analysis does not include psychotherapy codes because they do not correspond to codes billed by M/S providers, so there is nothing to compare them to in a parity analysis. The Medicare rate is included for comparison purposes.

AMFS (Office-Based Providers):

Service Code	M/S Physician	Psychiatrist	Medicare 1Q24
[redacted]	[redacted]	[redacted]	[redacted]

(2) In contracting with providers, the Plan also uses comparable factors, strategies, processes and evidentiary standards for MH/SUD providers and M/S providers, both as written and in operation. The key factors are the Unit Cost Trend Target and Provider Leverage. The fact that the Trend Target for standalone MH/SUD providers is set at the national level whereas the trend target for M/S providers is at the local market level does not render the process incomparable; it is because the MH/SUD network is managed by a national team whereas the M/S networks are managed at the market level. As for Provider Leverage, it is specific to the circumstances of the particular contract negotiation; a MH/SUD provider may have more leverage in a given negotiation than a M/S provider, and *vice versa*.

Even though the Plan's factors, processes and evidentiary standards for developing and maintaining the AMFS for MH/SUD rates are not more stringent than for M/S rates, the final Negotiated Charges resulting from contract negotiations may not reflect identical or more favorable MH/SUD rates in every instance. Provider groups and individual providers are free to negotiate rates different from the fee schedules, and the bargaining power they bring to such negotiations may result in Negotiated Charges that are different from the AMFS rates. According to DOL, HHS and Treasury, "[u]nder this analysis, the focus is not on whether the final result is the same for MH/SUD benefits as for medical/surgical benefits, but rather on whether the underlying processes, strategies, evidentiary standards, and other factors are in parity" (see FAQs part 45, April 2, 2021, at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf)

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer

is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
In summary, the factors, processes, strategies and evidentiary standards used to reimburse MH/SUD network providers are comparable to, and are applied no more stringently than, for M/S providers, both as written and in operation.
Referenced Policies and Documents (submitted with production as separate exhibits)
• [redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Reimbursement – Participating Provider (Facility) Benefit

Classifications/Subclassifications

- **In-network Inpatient**
- **In-network outpatient office visit subclassification**
- **In-network outpatient all other subclassification**
- **Emergency**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Plan Terms and/or Description of NQTL:

This NQTL is implemented by the plan's definition of Negotiated Charge, which 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).

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

Certificate of Coverage language:

[Negotiated charge

[For health coverage:

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.]

*[For **prescription** drug services:*

When you get a **prescription** drug, we have agreed to this amount for the **prescription** or paid this amount to the network pharmacy or third party vendor that provided it. The **negotiated charge** may include a rebate, additional service or risk charges and administrative fees. It may include additional amounts paid to or received from third parties under price guarantees.]]

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes

considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

[redacted]

The factors on which Negotiated Charges are based are:

[redacted]

[redacted]

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources:
Processes, strategies and/or evidentiary standards used to design and apply the NQTL

Strategy: Achieve 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 and drive membership growth.

Process: [redacted]

[redacted]

Evidentiary Standards

Index rates are referred to when developing rates for services that are paid according to a Medicare DRG or fee for service (AMFS) methodology.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written/In Operation

Comparability and Stringency Analysis:
Show if the processes, strategies, evidentiary standards and other factors used for MH/SUD are comparable to, and no more stringent than, those for M/S, as written and in operation

The factors, strategy, processes and evidentiary standards for determining reimbursement for MH/SUD facility-based providers are comparable to M/S facility-based providers, inasmuch as the Negotiated Charges are ultimately subject to individualized negotiations 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 Medicare DRGs are not available for MH/SUD 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 Negotiated Charge amounts 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 MH/SUD and M/S facility-based providers, and under some facility contracts those may be reimbursed on a fee for service bases using AMFS. For those shared codes, the AMFS rates are higher for MH/SUD providers than M/S providers. [redacted] For example, the rates for facility-based MH/SUD physicians are higher than for facility-based M/S physicians for the four most frequently billed shared codes, as shown by the chart below. The Medicare rate is included for comparison purposes.

AMFS (Facility-Based Providers):

Service Code	M/S Physician	Psychiatrist	Medicare 1Q24
[redacted]	[redacted]	[redacted]	[redacted]

Even though Aetna's factors, processes and evidentiary standards for developing and maintaining the AMFS for 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 are different from the AMFS rates.
According to DOL, HHS and Treasury, "[u]nder this analysis, the focus is not on whether the final result is the same for MH/SUD benefits as for medical/surgical benefits, but rather on whether the underlying processes, strategies, evidentiary standards, and other factors are in parity" (see FAQs part 45, April 2, 2021, at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf).

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer

is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
In summary, the factors, processes, strategies and evidentiary standards used to reimburse MH/SUD network facilities are comparable to, and are applied no more stringently than, for M/S providers, both as written and in operation.
Referenced Policies and Documents:
[redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Reimbursement - Non-Participating Provider Benefit

Classification/Subclassification

- **Out-of-network Inpatient**
- **Out-of-network Outpatient Office Visit Subclassification**
- **Out-of-network Outpatient All Other Subclassification**
- **Emergency**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Plan Terms and/or Description of NQTL:
This NQTL is implemented by the Recognized Charge, (previously referred to as the Allowable Amount), which is the amount of an out-of-network provider's charge that is eligible for coverage according to the method defined in the Certificate (typically a specified percentile of prevailing charges or a percentage of Medicare rates). The method for determining the Recognized Charge for a given plan is always the same for MH/SUD and M/S providers. The Recognized Charge depends on the geographic area where members get the service or supply.

M/S services NQTL applies to:	MH/SUD services NQTL applies to:
Applies to all M/S benefits delivered out of network	Applies to all MH/SUD benefits delivered out of network

Certificate of Coverage language:

[Allowable amount
This is the amount of an [**out-of-network] 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]
[Prescription drugs	[50%-200%] of average wholesale price (AWP)]
[Prescription drugs for gene-based, cellular and other innovative therapies (GCIT)	[50%-200%] of average wholesale price (AWP)]
[Dental expenses	[[50%-150%] of prevailing charge rate] [[50%-400%] of Aetna out-of-network rate (AONR)]]

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.] [Contact us or the [policyholder] for more information.]]

Special terms used:

- [Aetna out-of-network rates (AONR) are our standard rates used to begin contract talks with **providers** in a specific geographic area. For areas where we don't maintain AONR, we use [50%-400%] of the Medicare allowed rates.]
- [Average wholesale price (AWP) is the current average wholesale price of a **prescription** drug as listed in the Facts & Comparisons®, Medi-Span daily price updates or any other similar publication we choose to use.]

- [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 these when revised within [30-180 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
- For medications that are paid as a medical benefit instead of a pharmacy benefit, our rate may be [50%-100%] of the rates 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 [30-180 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

[Service or supply:	Reasonable amount rate is:
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]]]

Our reimbursement policies

We have the right to apply our reimbursement policies to all out-of-network services including involuntary 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.

-

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

[redacted]

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Sources:
Processes, strategies and/or evidentiary standards used to design and apply the NQTL

Strategy

Aetna compensates OON providers based on the terms of the member's plan, at the lesser of the billed charges or the recognized charge. The recognized charge is determined by a standard rate hierarchy that is the same for both MH/SUD and M/S.

Process

[redacted]

* Where the plan's OON rate is based on Medicare, all MH/SUD providers are paid at [redacted]. Where reimbursement is based on the Plan's standard OON rate then payment is tiered according to provider licensure:

	M/S	MH/SUD
[redacted]	Doctors	Doctors Clinical Psychologists
[redacted]	Nurse Practitioners Physician Assistants Certified Nurse Midwives	Nurse Practitioner Physician Assistant Psychiatric Nurses

	Clinical Nurse Specialists (e.g., Nurse Practitioner or Registered Nurse)	Drug and Alcohol Counselor Licensed Professional Counselor Marriage and Family Counselor Pastoral Counselor Psychological Examiner Social Worker
[redacted]	Audiologists Registered Dietician Genetic Counselors Massage Therapists Nutritionists Respiratory Therapists	n/a

For emergency and other involuntary OON services, applicable state and/or federal law is applied to determine the allowed amount and protect the member from balance billing.

Evidentiary Standards

CMS Medicare rates or the FAIR Health prevailing charges database are the benchmarks used to determine the Plan's standard OON rate. Medicare rates are also the standard for the Non-par reasonable rate. CMS' National Correct Coding Initiative (NCCI) and similar external materials about billing and coding practices, as well as generally accepted standards of medical practice, are also standards used to determine whether an OON bill is appropriately coded.

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

[redacted]

Plan/Issuer Response – As Written: The factors, strategy, process and evidentiary standards are comparable as written, and not more stringent for MH/SUD services, inasmuch as the plan's method for determining the recognized charge for OON services is the same for M/S and MH/SUD providers, and the same OON rate hierarchy tiers apply to MH/SUD and M/S claims. As for the payment tiers according to provider licensure type, the fact that there is a [redacted] tier for M/S providers whereas no MH/SUD providers are paid at [redacted] (even where their licensure requirements are comparable) shows that the recognized charge is more favorable to members, not less, for OON MH/SUD services.

Plan/Issuer Response – In Operation: Reviewing average OON reimbursement rates provides a way to compare how Aetna reimburses services from non-participating M/S and MH/SUD providers in operation.

Average recognized charges for M/S and MH/SUD physicians compared to Medicare: [redacted]

[redacted]

Average recognized charges for nonparticipating office-based providers:

Service Code	M/S Physician		MH/SUD Physician (Psychiatrist)		Medicare Allowed
	Avg. Allowed	Units Billed	Avg. Allowed	Units Billed	
99203	[redacted]				
99204					
99213					
99214					

[redacted]

[redacted]

[redacted]

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Summary of Conclusions:
In summary, the factors, processes, strategies and evidentiary standards used to reimburse OON MH/SUD providers are comparable to, and are applied no more stringently than, for OON M/S providers, both as written and in operation.
Referenced Policies and Documents:
[redacted]

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization – Exchange Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definitions

Generally based on medical practice and other clinical standards, utilization management (UM) tools are used primarily to control utilization and include the following:

Prior authorization (PA) requires that the prescribed use of a drug be evaluated for medical necessity before the prescription is covered.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Cost-effectiveness	Cost-effectiveness

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia

MED/SURG	MH/SUD

Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement

Applicable Sources and Evidentiary Standards for Prescription Drug Utilization Management Review Process

MED/SURG	MH/SUD
CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)	CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)
[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P]	[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P
[CVS CAREMARK IRR P&P] Document ID: PAR-0010]	[CVS CAREMARK IRR P&P; Document ID: PAR-0010]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Methodology

Comparative analysis of the application of factors as written was performed via a review of:

- utilization management policies and procedures
- samples of drug information documents, therapeutic class reviews and prior authorization criteria
- committee's policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the application of a PA, ST and/or QL on a drug to confirm that its use will follow the evidence-based drug uses. PA is applied when evidence-based drug use indicates that a diagnosis requires monitoring of the patient response, or additional supportive therapy is appropriate. ST is applied when appropriate alternatives are available. QL is applied when there is evidence that long-term and/or
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	unsupervised use of a drug may compromise the patient's safety.
	External clinical experts	
	Similar drugs	
Cost-effectiveness	Similar drugs	Sources inform whether it is cost-effective to use PA, ST and/or QL. Similar drugs that have PA, ST and/or QL provide clinical context for the application of the limitation and consistency. Utilization trend reports indicate whether it is cost-effective to operationalize the PA, ST and/or QL.
	Utilization trend reports	
	Applicable manufacturer agreement	

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The UM Clinical Development team drafts UM NQTL requirements that include coverage for use supported by evidence-based medicine and standard of care sources.
- The Formulary Review Committee (FRC), meets regularly to discuss and review drug information and makes recommendations for prior authorization for the P&T Committee's review and approval.
- Standard UM NQTLs are reviewed internally by a CVS Caremark Medical Director, and externally by external clinical experts coordinated through the Clinical Program Oversight (CPO) review process.
- The P&T Committee reviews and approves the UM NQTLs.

No separate policies or procedures exist with respect to UM NQTLs for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; both drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to MED/SURG drugs. The meeting minutes show that these experts evaluate and consider the factors for applying UM NQTLs in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

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 the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. Age restrictions are applied to MH/SUD or MED/SURG drugs if clinical evidence indicates a drug is potentially harmful or not effective in a population that can be defined by age, and these restrictions were found in the sample prior authorization criteria reviewed. The P&T Committee members use these drug information documents,

therapeutic class reviews and presentations to make informed decisions and vote on recommendations using the same process and equally weighing applicable factors and sources for formulary UM NQTLs considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

As Written Comparative Analysis for Prescription Drug Utilization Management Review Process

The CVS Caremark utilization management review program is administered by the CVS Caremark Clinical Operations unit. Consistent with CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois), 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 MED/SURG conditions or diseases.
Providers can submit coverage requests subject to utilization management electronically, by phone, fax, or in writing. CVS Caremark utilizes and accepts the Illinois Uniform Electronic Prior Authorization form which is available online at www.caremark.com. Requests are accepted 24 hours a day.
Representatives may be utilized to input data from coverage review requests into CVS Caremark's Clinical Administration System (CAS) system. An automated algorithm will determine if such data conforms to pre-established criteria for coverage. If the algorithm determines that the data conforms to the plan criteria for coverage, an approval letter will be systematically generated. If the data does not conform to the criteria for coverage, the request will be forwarded to a pharmacist for further review. In addition, if any data on the PA request is unclear, the request will be forwarded to a licensed practical nurse or pharmacist for further review. Reviews may also be performed by licensed pharmacists who are in good standing, if required, by the state in which they work.
Non-clinical or administrative denials are completed by a representative under the supervision of a licensed health care professional. Clinical denials are rendered by a board-certified physician reviewer who possesses a current and valid nonrestricted license in any United States jurisdiction.
The Clinical Operations unit will make a determination and give written notice to the provider and plan member regarding a determination involving prior authorizations or step therapy exception requests as fast as the plan member's condition requires and following the following timeframes:

a. Urgent pre-service reviews will be completed within 24 hours from receipt of request.

b. Non-urgent pre-service Reviews will be completed within 72 hours from receipt of request.

CVS Caremark has established an Inter-Rater Reliability process for monitoring the consistent application of clinical guidelines across utilization review decisions.

Plan/Issuer Response – In Operation:

Testing Methodology

The processed input drug coverage extract file was analyzed as follows:

- Drugs with formulary UM NQTLs were grouped into MH, SUD and MED/SURG drug types, counted, and totals were used to calculate the percentages on each type.
- Drugs with formulary UM NQTLs in the MH/SUD and MED/SURG types were grouped by therapeutic class, counted, and the totals were used to calculate percentages on each class.
- Samples of drug classes for chronic MED/SURG conditions were chosen as comparators. (See Appendix 3)
- Comparisons were performed at the drug class level, by count and percent, and by the factors considered and applied in each of the classes within each of the MH/SUD and MED/SURG drug types.

In Operation Results

Prior Authorization Drug Type Results

AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Count	2,809	609	120
PA Count	970	158	12
PA Percent	**34.5%**	**25.9%**	**10.0%**

Prior Authorization Drug Class Comparison Results

AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

MED/SURG Drug Class Comparators	Total Count	PA Count	PA Percent
DIABETES	99	39	39%
ANTIHYPERTENSIVES	153	1	1%
ANTIHYPERLIPIDEMICS	57	10	18%
ASTHMA/COPD	72	5	7%
OPIOIDS	97	96	99%
ANTI-INFLAMMATORY	77	34	44%
MIGRAINE	36	8	22%

MH Drug Classes	Total Count	PA Count	PA Percent
ADHD	107	3	3%
ANXIETY	51	7	14%
BIPOLAR/SCHIZOPHRENIA	145	11	8%
DEPRESSION	139	58	42%
ENDOCRINE REGULATION	40	36	90%
NEUROCOGNITIVE DISORDERS	91	26	29%
SLEEP-WAKE DISORDERS	36	17	47%

ANTICOAGULANTS	49	0	0%
OPHTHALMICS	84	3	4%
ACNE	30	15	50%

SUD Drug Classes	Total Count	PA Count	PA Percent
ALCOHOL USE DISORDER (AUD)	55	7	13%
OPIOID USE DISORDER (OUD)	40	0	0%
TOBACCO USE DISORDER (TUD)	25	5	20%

In Operation Results for Prescription Drug Utilization Management Review Process

Approval/Denial Rates – Prior Authorizations

AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Requests	671	32	0
Total Approvals	483	26	0
Total Denials	188	6	0
Approval Percent	72.0%	81.3%	0%
Denial Percent	28.0%	18.8%	0%

COMPARABILITY ANALYSIS

In operation, the prior authorization denial rate of 18.8% for MH drug requests is lower than the prior authorization denial rate of 28.0% for Med/Surg drug requests.

INTERRATER RELIABILITY REVIEWS

To evaluate the quality, accuracy, and consistency among clinical pharmacists' reviews of Prior Authorizations, Aetna's delegated UR agent, Caremark, conducts Inter-Rater Reliability reviews on random samples of prior authorization cases following methodology set forth by National Committee for Quality Assurance (NCQA).

Results

During the audit period of July 1, 2023, through June 30, 2024, a total of 215 prior authorization determinations were reviewed consistent with the Caremark Prior Authorization Inter-Rater Reliability (IRR) Process policy. Cases reviewed during this audit period resulted in an agreement rate of 99.5%. The results demonstrate a consistent adherence to prior authorization policies and clinical decision making with respect to prior authorization criteria and determinations.

Criteria for the IRR process is selected without regard to the specific therapeutic classification of drug. The sample selected may include mental health / substance use disorder and medical surgical drugs. There is no separate process to target MH/SUD or MS for review.

Stringency of coverage requests reviews analysis:

To demonstrate the in-operations parity with respect to reviewer activities evaluating Prior Authorization and Step Therapy coverage determinations, Aetna audited a random sample of denied cases across the MH/SUD and Med Surg. classification of drugs. Quality Assurance auditors utilized the Clinical Adjudication System and other supporting systems to review the coverage determination sample. For each question described in the methodology below the auditor reviewed the user's work to determine whether the initial review correctly followed the department's expectations regarding specific tasks related to the coverage request and process review.

The methodology and results of that analysis are described below.

Methodology

- A random sample of 20 coverage determination cases were selected for all formularies.
- Prior authorization 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* Med/Surg 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 indicated to treated either a MH/SUD or Med Surg condition.
- The universe of eligible Med/Surg cases for comparison to MH cases included requests for analgesics, anti-diabetic medications, ophthalmic agents, migraine products, anti-asthmatic agents and dermatological products.

- Following 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?
    - Was the decision turn-around time in compliance with policy requirements?
- Each case was subject to an audit by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.
- The selection criteria and sample composition was as follows:

Drug Classification	Utilization Management classification	Count
MH*	Prior Authorization	5
MH*	Step Therapy	5
Medical Surgical	Prior Authorization	5
Medical Surgical	Step Therapy	5

*No Prior Authorizations or Step Therapy denials were identified for SUD drugs

Results

The results of the audit were that all 20 audit samples met expectations and when MH cases were compared to Med/Surg 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 correct criteria was selected and used, the criteria questions were answered accurately and completely, 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 with the exception of one case involving a standard review for a Med/Surg drug.

The review of the cases demonstrated that the process for reviews was consistent across all prior authorization requests for Mental Health and MED/SURG cases. In every case, the health care professional responsible for the determination was a physician. There were no peer-to-peer discussions requested in any of the samples reviewed.

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Testing of the formulary prior authorization NQTL shows that overall, it is applied to a lower percentage of MH drugs and a lower percentage of SUD drugs compared to MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of UM NQTLs revealed that the factors and the sources are not used more stringently for MH/SUD compared to MED/SURG drugs and justify the current application of UM NQTLs to some of the drugs on this formulary.

In Conclusion for the Prescription Drug Utilization Management Review Process and taking into consideration the approval and denial rates for prior authorization and step therapy the ongoing interrater reviews and the in-operation audits conducted on MH and MED/SURG

drugs, the results from in-operation review demonstrated that the prior authorization process is being conducted and executed uniformly consistent with the policies and procedures and that the policies were not applied more stringently to reviews involving MH drugs as compared to reviews for Med/Surg drugs.
The information provided in steps 1-4 is sufficient to conclude compliance with MH Parity requirements.

This analysis has demonstrated that the application of prior authorization as a NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions.

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained. Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:
X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:
X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports. The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization – Standard Opt Out Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definitions

Generally based on medical practice and other clinical standards, utilization management (UM) tools are used primarily to control utilization and include the following:

Prior authorization (PA) requires that the prescribed use of a drug be evaluated for medical necessity before the prescription is covered.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Cost-effectiveness	Cost-effectiveness

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia

MED/SURG	MH/SUD

Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement

Applicable Sources and Evidentiary Standards for Prescription Drug Utilization Management Review Process

MED/SURG	MH/SUD
CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)	CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)
[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P]	[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P
[CVS CAREMARK IRR P&P] Document ID: PAR-0010]	[CVS CAREMARK IRR P&P; Document ID: PAR- 0010]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.
Plan/Issuer Response – As Written:

Methodology

Comparative analysis of the application of factors as written was performed via a review of:

- utilization management policies and procedures
- samples of drug information documents, therapeutic class reviews and prior authorization criteria
- committee's policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the application of a PA, ST and/or QL on a drug to confirm that its use will follow the evidence-based drug uses. PA is applied when evidence-based drug use indicates that a diagnosis requires monitoring of the patient response, or additional supportive therapy is appropriate. ST is applied when appropriate alternatives are available. QL is applied when there is evidence that long-term and/or
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	unsupervised use of a drug may compromise the patient's safety.
	External clinical experts	
	Similar drugs	
Cost-effectiveness	Similar drugs	Sources inform whether it is cost-effective to use PA, ST and/or QL. Similar drugs that have PA, ST and/or QL provide clinical context for the application of the limitation and consistency. Utilization trend reports indicate whether it is cost-effective to operationalize the PA, ST and/or QL.
	Utilization trend reports	
	Applicable manufacturer agreement	

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The UM Clinical Development team drafts UM NQTL requirements that include coverage for use supported by evidence-based medicine and standard of care sources.
- The Formulary Review Committee (FRC), meets regularly to discuss and review drug information and makes recommendations for prior authorization for the P&T Committee's review and approval.
- Standard UM NQTLs are reviewed internally by a CVS Caremark Medical Director, and externally by external clinical experts coordinated through the Clinical Program Oversight (CPO) review process.
- The P&T Committee reviews and approves the UM NQTLs.

No separate policies or procedures exist with respect to UM NQTLs for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; both drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to MED/SURG drugs. The meeting minutes show that these experts evaluate and consider the factors for applying UM NQTLs in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

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 the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. Age restrictions are applied to MH/SUD or MED/SURG drugs if clinical evidence indicates a drug is potentially harmful or not effective in a population that can be defined by age, and these restrictions were found in the sample prior authorization criteria reviewed. The P&T Committee members use these drug information documents,

therapeutic class reviews and presentations to make informed decisions and vote on recommendations using the same process and equally weighing applicable factors and sources for formulary UM NQTLs considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

As Written Comparative Analysis for Prescription Drug Utilization Management Review Process

The CVS Caremark utilization management review program is administered by the CVS Caremark Clinical Operations unit. Consistent with CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois), 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 MED/SURG conditions or diseases.
Providers can submit coverage requests subject to utilization management electronically, by phone, fax, or in writing. CVS Caremark utilizes and accepts the Illinois Uniform Electronic Prior Authorization form which is available online at www.caremark.com. Requests are accepted 24 hours a day.
Representatives may be utilized to input data from coverage review requests into CVS Caremark's Clinical Administration System (CAS) system. An automated algorithm will determine if such data conforms to pre-established criteria for coverage. If the algorithm determines that the data conforms to the plan criteria for coverage, an approval letter will be systematically generated. If the data does not conform to the criteria for coverage, the request will be forwarded to a pharmacist for further review. In addition, if any data on the PA request is unclear, the request will be forwarded to a licensed practical nurse or pharmacist for further review. Reviews may also be performed by licensed pharmacists who are in good standing, if required, by the state in which they work.
Non-clinical or administrative denials are completed by a representative under the supervision of a licensed health care professional. Clinical denials are rendered by a board-certified physician reviewer who possesses a current and valid nonrestricted license in any United States jurisdiction.
The Clinical Operations unit will make a determination and give written notice to the provider and plan member regarding a determination involving prior authorizations or step therapy exception requests as fast as the plan member's condition requires and following the following timeframes:

a. Urgent pre-service reviews will be completed within 24 hours from receipt of request.

b. Non-urgent pre-service Reviews will be completed within 72 hours from receipt of request.

CVS Caremark has established an Inter-Rater Reliability process for monitoring the consistent application of clinical guidelines across utilization review decisions.

Plan/Issuer Response – In Operation:

Testing Methodology

The processed input drug coverage extract file was analyzed as follows:

- Drugs with formulary UM NQTLs were grouped into MH, SUD and MED/SURG drug types, counted, and totals were used to calculate the percentages on each type.
- Drugs with formulary UM NQTLs in the MH/SUD and MED/SURG types were grouped by therapeutic class, counted, and the totals were used to calculate percentages on each class.
- Samples of drug classes for chronic MED/SURG conditions were chosen as comparators. (See Appendix 3)
- Comparisons were performed at the drug class level, by count and percent, and by the factors considered and applied in each of the classes within each of the MH/SUD and MED/SURG drug types.

In Operation Results

Prior Authorization Drug Type Results

AETNA of ILLINOIS - Standard Opt Out Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Count	4,474	867	123
PA Count	1458	136	0
PA Percent	**32.6%**	**15.7%**	**0.0%**

Prior Authorization Drug Class Comparison Results

AETNA of ILLINOIS - Standard Opt Out Formulary - 2024

MED/SURG Drug Class Comparators	Total Count	PA Count	PA Percent
DIABETES	227	21	9%
ANTIHYPERTENSIVES	179	5	3%
ANTIHYPERLIPIDEMICS	77	21	27%
ASTHMA/COPD	109	12	11%
OPIOIDS	212	211	100%
ANTI-INFLAMMATORY	103	44	43%
MIGRAINE	49	3	6%
ANTICOAGULANTS	62	0	0%
OPHTHALMICS	134	10	7%

MH Drug Classes	Total Count	PA Count	PA Percent
ADHD	169	0	0%
ANXIETY	64	0	0%
BIPOLAR/SCHIZOPHRENIA	223	23	10%
DEPRESSION	166	10	6%
ENDOCRINE REGULATION	74	70	95%
NEUROCOGNITIVE DISORDERS	120	13	11%
SLEEP-WAKE DISORDERS	51	20	39%
SUD Drug Classes	**Total Count**	**PA Count**	**PA Percent**
ALCOHOL USE DISORDER (AUD)	58	0	0%

ACNE	60	38	63%	OPIOID USE DISORDER (OUD)	40	0	0%
				TOBACCO USE DISORDER (TUD)	25	0	0%

In Operation Results for Prescription Drug Utilization Management Review Process

Approval/Denial Rates – Prior Authorizations

AETNA of ILLINOIS - Aetna Standard Opt Out Formulary – 2024

Drug Type	MED/SURG	MH	SUD
Total Requests	154	2	0
Total Approvals	127	2	0
Total Denials	27	0	0
Approval Percent	82.5%	100%	0%
Denial Percent	17.5%	0%	0%

COMPARABILITY ANALYSIS
In operation, the prior authorization denial rate of 0% for MH drug requests is lower than the prior authorization denial rate of 17.5% for Med/Surg drug requests.

INTERRATER RELIABILITY REVIEWS
To evaluate the quality, accuracy, and consistency among clinical pharmacists' reviews of Prior Authorizations, Aetna's delegated UR agent, Caremark, conducts Inter-Rater Reliability reviews on random samples of prior authorization cases following methodology set forth by National Committee for Quality Assurance (NCQA).

Results
During the audit period of July 1, 2023, through June 30, 2024, a total of 215 prior authorization determinations were reviewed consistent with the Caremark Prior Authorization Inter-Rater Reliability (IRR) Process policy. Cases reviewed during this audit period resulted in an agreement rate of 99.5%. The results demonstrate a consistent adherence to prior authorization policies and clinical decision making with respect to prior authorization criteria and determinations.

Criteria for the IRR process is selected without regard to the specific therapeutic classification of drug. The sample selected may include mental health / substance use disorder and medical surgical drugs. There is no separate process to target MH/SUD or MS for review.

Stringency of coverage requests reviews analysis:

To demonstrate the in-operations parity with respect to reviewer activities evaluating Prior Authorization and Step Therapy coverage determinations, Aetna audited a random sample of denied cases across the MH/SUD and Med Surg. classification of drugs. Quality Assurance auditors utilized the Clinical Adjudication System and other supporting systems to review the coverage determination sample. For each question described in the methodology below the auditor reviewed the user's work to determine whether the initial review correctly followed the department's expectations regarding specific tasks related to

the coverage request and process review.

The methodology and results of that analysis are described below.

Methodology

- A random sample of 20 coverage determination cases were selected for all formularies.
- Prior authorization 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* Med/Surg 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 indicated to treated either a MH/SUD or Med Surg condition.
- The universe of eligible Med/Surg cases for comparison to MH cases included requests for analgesics, anti-diabetic medications, ophthalmic agents, migraine products, anti-asthmatic agents and dermatological products.

- Following 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?
    - Was the decision turn-around time in compliance with policy requirements?
- Each case was subject to an audit by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.
- The selection criteria and sample composition was as follows:

Drug Classification	Utilization Management classification	Count
MH*	Prior Authorization	5
MH*	Step Therapy	5
Medical Surgical	Prior Authorization	5
Medical Surgical	Step Therapy	5

*No Prior Authorizations or Step Therapy denials were identified for SUD drugs

Results

The results of the audit were that all 20 audit samples met expectations and when MH cases were compared to Med/Surg 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 correct criteria was selected and used, the criteria questions were answered accurately and completely, 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 with the exception of one case involving a standard review for a Med/Surg drug.

The review of the cases demonstrated that the process for reviews was consistent across all prior authorization requests for Mental Health and MED/SURG cases. In every case, the health care professional responsible for the determination was a physician. There were no peer-to-peer discussions requested in any of the samples reviewed.

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Testing of the formulary prior authorization NQTL shows that overall, it is applied to a lower percentage of MH drugs and a lower percentage of SUD drugs compared to MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of UM NQTLs revealed that the factors and the sources are not used more stringently for MH/SUD compared to MED/SURG drugs and justify the current application of UM NQTLs to some of the drugs on this formulary.

In Conclusion for the Prescription Drug Utilization Management Review Process and taking into consideration the approval and denial rates for prior authorization and step therapy the ongoing interrater reviews and the in-operation audits conducted on MH and MED/SURG drugs, the results from in-operation review demonstrated that the prior authorization process is being conducted and executed uniformly consistent with the policies and procedures and that the policies were not applied more stringently to reviews involving MH drugs as compared to reviews for Med/Surg drugs.
The information provided in steps 1-4 is sufficient to conclude compliance with MH Parity requirements.

This analysis has demonstrated that the application of prior authorization as a NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions.

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained. Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:

X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:

X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports. The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Prior Authorization – Advanced Control Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definitions

Generally based on medical practice and other clinical standards, utilization management (UM) tools are used primarily to control utilization and include the following:

Prior authorization (PA) requires that the prescribed use of a drug be evaluated for medical necessity before the prescription is covered.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Cost-effectiveness	Cost-effectiveness

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia

MED/SURG	MH/SUD
Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement

Applicable Sources and Evidentiary Standards for Prescription Drug Utilization Management Review Process

MED/SURG	MH/SUD
CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)	CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)
[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P]	[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P
[CVS CAREMARK IRR P&P] Document ID: PAR-0010]	[CVS CAREMARK IRR P&P; Document ID: PAR- 0010]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Methodology

Comparative analysis of the application of factors as written was performed via a review of:

- utilization management policies and procedures
- samples of drug information documents, therapeutic class reviews and prior authorization criteria
- committee's policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the application of a PA, ST and/or QL on a drug to confirm that its use will follow the evidence-based drug uses. PA is applied when evidence-based drug use indicates that a diagnosis requires monitoring of the patient response, or additional supportive therapy is appropriate. ST is applied when appropriate alternatives are available. QL is applied when there is evidence that long-term and/or
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	unsupervised use of a drug may compromise the patient's safety.
	External clinical experts	
	Similar drugs	
Cost-effectiveness	Similar drugs	Sources inform whether it is cost-effective to use PA, ST and/or QL. Similar drugs that have PA, ST and/or QL provide clinical context for the application of the limitation and consistency. Utilization trend reports indicate whether it is cost-effective to operationalize the PA, ST and/or QL.
	Utilization trend reports	
	Applicable manufacturer agreement	

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The UM Clinical Development team drafts UM NQTL requirements that include coverage for use supported by evidence-based medicine and standard of care sources.[i]
- The Formulary Review Committee (FRC), meets regularly to discuss and review drug information and makes recommendations for prior authorization for the P&T Committee's review and approval.
- Standard UM NQTLs are reviewed internally by a CVS Caremark Medical Director, and externally by external clinical experts coordinated through the Clinical Program Oversight (CPO) review process.
- The P&T Committee reviews and approves the UM NQTLs.

No separate policies or procedures exist with respect to UM NQTLs for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; both drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to MED/SURG drugs. The meeting minutes show that these experts evaluate and consider the factors for applying UM NQTLs in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

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 the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. Age restrictions are applied to MH/SUD or MED/SURG drugs if clinical evidence indicates a drug is potentially harmful or not effective in a population that can be defined by age, and these restrictions were found in the sample prior authorization criteria reviewed. The P&T Committee members use these drug information documents,

therapeutic class reviews and presentations to make informed decisions and vote on recommendations using the same process and equally weighing applicable factors and sources for formulary UM NQTLs considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

As Written Comparative Analysis for Prescription Drug Utilization Management Review Process

The CVS Caremark utilization management review program is administered by the CVS Caremark Clinical Operations unit. Consistent with CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois), 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 MED/SURG conditions or diseases.
Providers can submit coverage requests subject to utilization management electronically, by phone, fax, or in writing. CVS Caremark utilizes and accepts the Illinois Uniform Electronic Prior Authorization form which is available online at www.caremark.com. Requests are accepted 24 hours a day.
Representatives may be utilized to input data from coverage review requests into CVS Caremark's Clinical Administration System (CAS) system. An automated algorithm will determine if such data conforms to pre-established criteria for coverage. If the algorithm determines that the data conforms to the plan criteria for coverage, an approval letter will be systematically generated. If the data does not conform to the criteria for coverage, the request will be forwarded to a pharmacist for further review. In addition, if any data on the PA request is unclear, the request will be forwarded to a licensed practical nurse or pharmacist for further review. Reviews may also be performed by licensed pharmacists who are in good standing, if required, by the state in which they work.
Non-clinical or administrative denials are completed by a representative under the supervision of a licensed health care professional. Clinical denials are rendered by a board-certified physician reviewer who possesses a current and valid nonrestricted license in any United States jurisdiction.
The Clinical Operations unit will make a determination and give written notice to the provider and plan member regarding a determination involving prior authorizations or step therapy exception requests as fast as the plan member's condition requires and following the following timeframes:

a. Urgent pre-service reviews will be completed within 24 hours from receipt of request.

b. Non-urgent pre-service Reviews will be completed within 72 hours from receipt of request.

CVS Caremark has established an Inter-Rater Reliability process for monitoring the consistent application of clinical guidelines across utilization review decisions.

Plan/Issuer Response – In Operation:

Testing Methodology

The processed input drug coverage extract file was analyzed as follows:

- Drugs with formulary UM NQTLs were grouped into MH, SUD and MED/SURG drug types, counted, and totals were used to calculate the percentages on each type.
- Drugs with formulary UM NQTLs in the MH/SUD and MED/SURG types were grouped by therapeutic class, counted, and the totals were used to calculate percentages on each class.
- Samples of drug classes for chronic MED/SURG conditions were chosen as comparators. (See Appendix 3)
- Comparisons were performed at the drug class level, by count and percent, and by the factors considered and applied in each of the classes within each of the MH/SUD and MED/SURG drug types.

In Operation Results

Prior Authorization Drug Type Results

AETNA of ILLINOIS - Advanced Control Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Count	3,776	749	122
PA Count	1556	190	12
PA Percent	**41.2%**	**25.4%**	**9.8%**

Prior Authorization Drug Class Comparison Results

AETNA of ILLINOIS - Advanced Control Formulary - 2024

MED/SURG Drug Class Comparators	Total Count	PA Count	PA Percent
DIABETES	128	53	41%
ANTIHYPERTENSIVES	162	2	1%
ANTIHYPERLIPIDEMICS	62	9	15%
ASTHMA/COPD	73	12	16%
OPIOIDS	137	136	99%
ANTI-INFLAMMATORY	95	44	46%
MIGRAINE	55	26	47%

MH Drug Classes	Total Count	PA Count	PA Percent
ADHD	130	1	1%
ANXIETY	64	0	0%
BIPOLAR/SCHIZOPHRENIA	197	16	8%
DEPRESSION	140	55	39%
ENDOCRINE REGULATION	60	56	93%
NEUROCOGNITIVE DISORDERS	116	36	31%
SLEEP-WAKE DISORDERS	42	26	62%

ANTICOAGULANTS	40	0	0%
OPHTHALMICS	91	7	8%
ACNE	49	32	65%

SUD Drug Classes	Total Count	PA Count	PA Percent
ALCOHOL USE DISORDER (AUD)	57	7	12%
OPIOID USE DISORDER (OUD)	40	0	0%
TOBACCO USE DISORDER (TUD)	25	5	20%

In Operation Results for Prescription Drug Utilization Management Review Process

Approval/Denial Rates – Prior Authorizations
AETNA of ILLINOIS - Aetna Advanced Control Formulary – 2024

Drug Type	MED/SURG	MH	SUD
Total Requests	2394	234	0
Total Approvals	1782	202	0
Total Denials	612	32	0
Approval Percent	74.4%	86.3%	0%
Denial Percent	25.6%	13.7%	0%

COMPARABILITY ANALYSIS
In operation, the prior authorization denial rate of 13.7% for MH drug requests is lower than the prior authorization denial rate of 25.6% for Med/Surg drug requests.

INTERRATER RELIABILITY REVIEWS

To evaluate the quality, accuracy, and consistency among clinical pharmacists' reviews of Prior Authorizations, Aetna's delegated UR agent, Caremark, conducts Inter-Rater Reliability reviews on random samples of prior authorization cases following methodology set forth by National Committee for Quality Assurance (NCQA).

Results
During the audit period of July 1, 2023, through June 30, 2024, a total of 215 prior authorization determinations were reviewed consistent with the Caremark Prior Authorization Inter-Rater Reliability (IRR) Process policy[1]. Cases reviewed during this audit period resulted in an agreement rate of 99.5%. The results demonstrate a consistent adherence to prior authorization policies and clinical decision making with respect to prior authorization criteria and determinations.

Criteria for the IRR process is selected without regard to the specific therapeutic classification of drug. The sample selected may include mental health / substance use disorder and medical surgical drugs. There is no separate process to target MH/SUD or MS for review.

Stringency of coverage requests reviews analysis:

To demonstrate the in-operations parity with respect to reviewer activities evaluating Prior Authorization and Step Therapy coverage determinations, Aetna audited a random sample of denied cases across the MH/SUD and Med Surg. classification of drugs. Quality Assurance auditors utilized the Clinical Adjudication System and other supporting systems to review the coverage determination sample. For each question described in the methodology below the auditor reviewed the user's work to determine whether the initial review correctly followed the department's expectations regarding specific tasks related to the coverage request and process review.

The methodology and results of that analysis are described below.

Methodology

- A random sample of 20 coverage determination cases were selected for all formularies.
- Prior authorization 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* Med/Surg 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 indicated to treated either a MH/SUD or Med Surg condition.
- The universe of eligible Med/Surg cases for comparison to MH cases included requests for analgesics, anti-diabetic medications, ophthalmic agents, migraine products, anti-asthmatic agents and dermatological products.

- Following 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?
    - Was the decision turn-around time in compliance with policy requirements?
- Each case was subject to an audit by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.
- The selection criteria and sample composition was as follows:

Drug Classification	Utilization Management classification	Count
MH*	Prior Authorization	5
MH*	Step Therapy	5
Medical Surgical	Prior Authorization	5
Medical Surgical	Step Therapy	5

*No Prior Authorizations or Step Therapy denials were identified for SUD drugs

Results

The results of the audit were that all 20 audit samples met expectations and when MH cases were compared to Med/Surg 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 correct criteria was selected and used, the criteria questions were answered accurately and completely, 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 with the exception of one case involving a standard review for a Med/Surg drug.

The review of the cases demonstrated that the process for reviews was consistent across all prior authorization requests for Mental Health and MED/SURG cases. In every case, the health care professional responsible for the determination was a physician. There were no peer-to-peer discussions requested in any of the samples reviewed.

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Testing of the formulary prior authorization NQTL shows that overall, it is applied to a lower percentage of MH drugs and a lower percentage of SUD drugs compared to MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of UM NQTLs revealed that the factors and the sources are not used more stringently for MH/SUD compared to MED/SURG drugs and justify the current application of UM NQTLs to some of the drugs on this formulary.

In Conclusion for the Prescription Drug Utilization Management Review Process and taking into consideration the approval and denial rates for prior authorization and step therapy the ongoing interrater reviews and the in-operation audits conducted on MH and MED/SURG drugs, the results from in-operation review demonstrated that the prior authorization process is being conducted and executed uniformly consistent with the policies and procedures and that the policies were not applied more stringently to reviews involving MH drugs as compared to reviews for Med/Surg drugs.
The information provided in steps 1-4 is sufficient to conclude compliance with MH Parity requirements.

This analysis has demonstrated that the application of prior authorization as a NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions.

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

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Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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Medical Directors, DO

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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
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Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained.
Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:
X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:
X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports. The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Formulary Tiering – Exchange Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definition

A formulary divides drugs into ranked tiers that may be based on a drug's cost, generic or brand status, and/or preferred or non-preferred status. The tiers may determine what the member pays for a covered prescription drug. This NQTL addresses how the MH/SUD and MED/SURG drugs are placed on the formulary tiers.

Special rule for multi-tiered prescription drug benefits: Multi-tiered drug formularies involve different levels of drugs that are classified based primarily on cost, the lowest-tier (Tier 1) drugs having the lowest cost-sharing. If a plan or issuer applies different levels of financial requirements to different tiers of prescription drug benefits, the plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with the rules for NQTLs and without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up. See 26 CFR54.9812- 1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), 45 CFR 146.136(c)(3)(iii).[i,ii]

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Specialty drug status	Specialty drug status
Drug pipeline	Drug pipeline
Cost-effectiveness	Cost-effectiveness
Regulatory requirements	Regulatory requirements

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia
Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement
Federal regulations and data	Federal regulations and data
Pipeline Reports	Pipeline Reports

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

As Written Comparative Analysis

Methodology

Comparative analysis of the application of factors as written was performed by Pharmacy Benefit Management (PBM) Pharmacists via a review of:

- formulary management policies and procedures
- samples of drug information documents and therapeutic class reviews
- committees' policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the placement of a drug in a tier. If the evidence-based drug use is safe and effective and it is cost effective, the drug is placed in a lower/preferred tier. Otherwise, a drug is added to a higher/non-preferred tier.
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	
	External clinical experts	
	Similar drugs	
Drug pipeline	Pipeline Reports	Pipeline information is considered to determine whether a drug will change moved to another tier when a generic version or a therapeutically superior/safer drug becomes available.
Cost-effectiveness	Available similar drugs	Lowest net cost influences how a branded drug within a therapeutic class will be placed in a preferred tier.
	Utilization trend reports	
	Applicable manufacturer agreement	
Specialty drug status*	US Food and Drug Administration labeling	Sources inform the placement of a drug in a specialty tier. If the evidence-based drug use is for difficult to treat chronic conditions, requiring close monitoring and education of the patient, and/or a high-cost drug requires patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer, and/or there is evidence that the drug needs to be dispensed from a specialty pharmacy, the drug is placed in a specialty tier.
	Centers for Medicare & Medicaid Services accepted drug compendia	
	Published peer-reviewed clinical literature, accepted clinical practice guidelines standards of care and government health agencies	
	Similar drugs	
Regulatory requirements	Federal regulations and data	Sources inform the placement of a drug on a tier according to drug type (generic drug is placed in generic tier, brand drug is placed in a brand tier, preventative drug is placed in a preventative drug tier).

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the formulary development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The Formulary Administration 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) 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 CVS Caremark Clinical Formulary team develops drug information documents using the sources outlined above.

- The P&T Committee reviews sources of appropriate information and tiering recommendations and approves formulary changes. The committee meets at least quarterly.

No separate policies or procedures exist with respect to formulary tiering for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow the same processes when considering MH/SUD and MED/SURG drugs. The minutes show that these experts evaluate and consider the factors for tier assignments in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

The sources and evidentiary standards vary depending on the drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. The P&T Committee members use these drug information documents, therapeutic class reviews and formulary presentations to make informed decisions and vote on recommendations using the same process and considering the same factors and sources for formulary and tiering considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The committee members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

Plan/Issuer Response – In Operation:

In Operation Comparative Analysis

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 MED/SURG 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. (See Appendix 3)

In Operation Results

Formulary Tier Descriptions

- Tier 0 = ACA Preventive Drugs
- Tier 1 = Preferred Generics

- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands and Generics
- Tier 4 = Preferred Specialty
- Tier 5 = Non-Preferred Specialty

Formulary Tiering by Drug Type
AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

Drug Type	Results							
	Tier 0	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total**	**Preferred**
MED/SURG	91	1518	197	595	357	51	2809	**77.0%**
	3.2%	54.0%	7.0%	21.2%	12.7%	1.8%		
	Tier 0	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total**	**Preferred**
MH	14	411	14	167	3	0	609	**72.6%**
	2.3%	67.5%	2.3%	27.4%	0.5%	0.0%		
	Tier 0	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total**	**Preferred**
SUD	19	80	18	3	0	0	120	**97.5%**
	15.8%	66.7%	15.0%	2.5%	0.0%	0.0%		

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

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 MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of the tiers revealed that the factors and the sources are not used differently or more stringently with respect to MH/SUD compared to MED/SURG drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs.

In conclusion, this analysis has demonstrated that in the determination of formulary tiering as an NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions. Moreover, as stated in the MHPAEA regulations, a plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with the rules for NQTLs and without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD benefits (see Special rule for multi-tiered prescription drug benefits).

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

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A, B, C, ... = the count of drugs of each type in preferred tiers
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:

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Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:

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Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports.[iv] The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

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Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

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A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definition

A formulary divides drugs into ranked tiers that may be based on a drug's cost, generic or brand status, and/or preferred or non-preferred status. The tiers may determine what the member pays for a covered prescription drug. This NQTL addresses how the MH/SUD and MED/SURG drugs are placed on the formulary tiers.

Special rule for multi-tiered prescription drug benefits: Multi-tiered drug formularies involve different levels of drugs that are classified based primarily on cost, the lowest-tier (Tier 1) drugs having the lowest cost-sharing. If a plan or issuer applies different levels of financial requirements to different tiers of prescription drug benefits, the plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with the rules for NQTLs and without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up. See 26 CFR54.9812- 1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), 45 CFR 146.136(c)(3)(iii).[i,ii]

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Specialty drug status	Specialty drug status
Drug pipeline	Drug pipeline
Cost-effectiveness	Cost-effectiveness
Regulatory requirements	Regulatory requirements

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia
Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement
Federal regulations and data	Federal regulations and data
Pipeline Reports	Pipeline Reports

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

As Written Comparative Analysis

Methodology

Comparative analysis of the application of factors as written was performed by Pharmacy Benefit Management (PBM) Pharmacists via a review of:

- formulary management policies and procedures
- samples of drug information documents and therapeutic class reviews
- committees' policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the placement of a drug in a tier. If the evidence-based drug use is safe and effective and it is cost effective, the drug is placed in a lower/preferred tier. Otherwise, a drug is added to a higher/non-preferred tier.
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	
	External clinical experts	
	Similar drugs	
Drug pipeline	Pipeline Reports	Pipeline information is considered to determine whether a drug will change moved to another tier when a generic version or a therapeutically superior/safer drug becomes available.
Cost-effectiveness	Available similar drugs	Lowest net cost influences how a branded drug within a therapeutic class will be placed in a preferred tier.
	Utilization trend reports	
	Applicable manufacturer agreement	
Specialty drug status*	US Food and Drug Administration labeling	Sources inform the placement of a drug in a specialty tier. If the evidence-based drug use is for difficult to treat chronic conditions, requiring close monitoring and education of the patient, and/or a high-cost drug requires patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer, and/or there is evidence that the drug needs to be dispensed from a specialty pharmacy, the drug is placed in a specialty tier.
	Centers for Medicare & Medicaid Services accepted drug compendia	
	Published peer-reviewed clinical literature, accepted clinical practice guidelines standards of care and government health agencies	
	Similar drugs	
Regulatory requirements	Federal regulations and data	Sources inform the placement of a drug on a tier according to drug type (generic drug is placed in generic tier, brand drug is placed in a brand tier, preventative drug is placed in a preventative drug tier).

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the formulary development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The Formulary Administration 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) 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 CVS Caremark Clinical Formulary team develops drug information documents using the sources outlined above.
- The P&T Committee reviews sources of appropriate information and tiering recommendations and approves formulary changes. The committee meets at least quarterly.

No separate policies or procedures exist with respect to formulary tiering for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow the same processes when considering MH/SUD and MED/SURG drugs. The minutes show that these experts evaluate and consider the factors for tier assignments in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

The sources and evidentiary standards vary depending on the drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures.The P&T Committee members use these drug information documents, therapeutic class reviews and formulary presentations to make informed decisions and vote on recommendations using the same process and considering the same factors and sources for formulary and tiering considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The committee members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

Plan/Issuer Response – In Operation:

In Operation Comparative Analysis

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 MED/SURG 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. (See Appendix 3)

In Operation Results

Formulary Tier Descriptions

- Tier 1 = Generics
- Tier 2 = Preferred Brands

- Tier 3 = Non-Preferred Brands
- Tier 4 = Specialty

Formulary Tiering by Drug Type
AETNA of ILLINOIS - Standard Opt Out Formulary - 2024

Drug Type	Results					
	Tier 1	**Tier 2**	**Tier 3**	**Tier 4**	**Total**	**Preferred**
MED/SURG	2306	394	913	861	4474	**60.4%**
	51.5%	8.8%	20.4%	19.2%		
	Tier 1	**Tier 2**	**Tier 3**	**Tier 4**	**Total**	**Preferred**
MH	633	62	140	32	867	**80.2%**
	73.0%	7.2%	16.1%	3.7%		
	Tier 1	**Tier 2**	**Tier 3**	**Tier 4**	**Total**	**Preferred**
SUD	97	25	1	0	123	**99.2%**
	78.9%	20.3%	0.8%	0.0%		

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

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 MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of the tiers revealed that the factors and the sources are not used differently or more stringently with respect to MH/SUD compared to MED/SURG drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs.

In conclusion, this analysis has demonstrated that in the determination of formulary tiering as an NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions. Moreover, as stated in the MHPAEA regulations, a plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with the rules for NQTLs and without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD benefits (see Special rule for multi-tiered prescription drug benefits).

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained. [iii] Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:

X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:

X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports.[iv] The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Formulary Tiering – Advanced Control Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definition

A formulary divides drugs into ranked tiers that may be based on a drug's cost, generic or brand status, and/or preferred or non-preferred status. The tiers may determine what the member pays for a covered prescription drug. This NQTL addresses how the MH/SUD and MED/SURG drugs are placed on the formulary tiers.

Special rule for multi-tiered prescription drug benefits: Multi-tiered drug formularies involve different levels of drugs that are classified based primarily on cost, the lowest-tier (Tier 1) drugs having the lowest cost-sharing. If a plan or issuer applies different levels of financial requirements to different tiers of prescription drug benefits, the plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with the rules for NQTLs and without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up. See 26 CFR54.9812- 1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), 45 CFR 146.136(c)(3)(iii).

Step 2:

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Factors

Definition of Factors (see Appendix 1)

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No separate policies or procedures exist with respect to formulary tiering for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow the same processes when considering MH/SUD and MED/SURG drugs. The minutes show that these experts evaluate and consider the factors for tier assignments in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

The sources and evidentiary standards vary depending on the drug and each drug class and are disease or condition specific; however, their level of evidence is the same and consistent with the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures.The P&T Committee members use these drug information documents, therapeutic class reviews and formulary presentations to make informed decisions and vote on recommendations using the same process and considering the same factors and sources for formulary and tiering considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The committee members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

Plan/Issuer Response – In Operation:

In Operation Comparative Analysis

Testing Methodology

The input drug coverage extract file was processed and analyzed as follows:

- Using the Medi-Span Generic Product Identifier (GPI)[i] 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 MED/SURG 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. (See Appendix 3)

In Operation Results

Formulary Tier Descriptions

- Tier 1 = Preferred Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands and Generics
- Tier 4 = Specialty

Formulary Tiering by Drug Type

AETNA of ILLINOIS - Advanced Control Formulary - 2024

Drug Type	Results					
MED/SURG	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Total**	**Preferred**
	1832	300	785	859	3776	**56.5%**
	48.5%	7.9%	20.8%	22.7%		
MH	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Total**	**Preferred**
	527	33	157	32	749	**74.8%**
	70.4%	4.4%	21.0%	4.3%		
SUD	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Total**	**Preferred**
	94	25	3	0	122	**97.5%**
	77.0%	20.5%	2.5%	0.0%		

Summary and Conclusion

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 MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of the tiers revealed that the factors and the sources are not used differently or more stringently with respect to MH/SUD compared to MED/SURG drugs, and the justification for placement of these drugs in the preferred or non-preferred tiers was consistent across both categories of drugs.

In conclusion, this analysis has demonstrated that in the determination of formulary tiering as an NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions. Moreover, as stated in the MHPAEA regulations, a plan complies with the mental health parity provisions if it establishes the different levels of financial requirements based on reasonable factors determined in accordance with the rules for NQTLs and without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD benefits (see Special rule for multi-tiered prescription drug benefits).

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained. [iii] Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:
X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:
X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports.[iv] The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Step Therapy-Exchange Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definitions

Generally based on medical practice and other clinical standards, utilization management (UM) tools are used primarily to control utilization and include the following:

Step therapy (ST) requires that preferred drugs be tried first before covering another non-preferred drug.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Cost-effectiveness	Cost-effectiveness

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia

MED/SURG	MH/SUD
Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement

Applicable Sources and Evidentiary Standards for Prescription Drug Utilization Management Review Process

MED/SURG	MH/SUD
CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)	CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)
[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P]	[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P
[CVS CAREMARK IRR P&P] Document ID: PAR-0010]	[CVS CAREMARK IRR P&P; Document ID: PAR-0010]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Methodology

Comparative analysis of the application of factors as written was performed via a review of:

- utilization management policies and procedures
- samples of drug information documents, therapeutic class reviews and prior authorization criteria
- committee's policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the application of a PA, ST and/or QL on a drug to confirm that its use will follow the evidence-based drug uses. PA is applied when evidence-based drug use indicates that a diagnosis requires monitoring of the patient response, or additional supportive therapy is appropriate. ST is applied when appropriate alternatives are available. QL is applied when there is evidence that long-term and/or
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	unsupervised use of a drug may compromise the patient's safety.
	External clinical experts	
	Similar drugs	
Cost-effectiveness	Similar drugs	Sources inform whether it is cost-effective to use PA, ST and/or QL. Similar drugs that have PA, ST and/or QL provide clinical context for the application of the limitation and consistency. Utilization trend reports indicate whether it is cost-effective to operationalize the PA, ST and/or QL.
	Utilization trend reports	
	Applicable manufacturer agreement	

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The UM Clinical Development team drafts UM NQTL requirements that include coverage for use supported by evidence-based medicine and standard of care sources.
- The Formulary Review Committee (FRC), meets regularly to discuss and review drug information and makes recommendations for prior authorization for the P&T Committee's review and approval.
- Standard UM NQTLs are reviewed internally by a CVS Caremark Medical Director, and externally by external clinical experts coordinated through the Clinical Program Oversight (CPO) review process.
- The P&T Committee reviews and approves the UM NQTLs.

No separate policies or procedures exist with respect to UM NQTLs for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; both drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to MED/SURG drugs. The meeting minutes show that these experts evaluate and consider the factors for applying UM NQTLs in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

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 the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. Age restrictions are applied to MH/SUD or MED/SURG drugs if clinical evidence indicates a drug is potentially harmful or not effective in a population that can be defined by age, and these restrictions were found in the sample prior authorization criteria reviewed. The P&T Committee members use these drug information documents,

therapeutic class reviews and presentations to make informed decisions and vote on recommendations using the same process and equally weighing applicable factors and sources for formulary UM NQTLs considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

As Written Comparative Analysis for Prescription Drug Utilization Management Review Process

The CVS Caremark utilization management review program is administered by the CVS Caremark Clinical Operations unit. Consistent with CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois), 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 MED/SURG conditions or diseases.
Providers can submit coverage requests subject to utilization management electronically, by phone, fax, or in writing. CVS Caremark utilizes and accepts the Illinois Uniform Electronic Prior Authorization form which is available online at www.caremark.com. Requests are accepted 24 hours a day.
Representatives may be utilized to input data from coverage review requests into CVS Caremark's Clinical Administration System (CAS) system. An automated algorithm will determine if such data conforms to pre-established criteria for coverage. If the algorithm determines that the data conforms to the plan criteria for coverage, an approval letter will be systematically generated. If the data does not conform to the criteria for coverage, the request will be forwarded to a pharmacist for further review. In addition, if any data on the PA request is unclear, the request will be forwarded to a licensed practical nurse or pharmacist for further review. Reviews may also be performed by licensed pharmacists who are in good standing, if required, by the state in which they work.
Non-clinical or administrative denials are completed by a representative under the supervision of a licensed health care professional. Clinical denials are rendered by a board-certified physician reviewer who possesses a current and valid nonrestricted license in any United States jurisdiction.
The Clinical Operations unit will make a determination and give written notice to the provider and plan member regarding a determination involving prior authorizations or step therapy exception requests as fast as the plan member's condition requires and following the following timeframes:

a. Urgent pre-service reviews will be completed within 24 hours from receipt of request.

b. Non-urgent pre-service Reviews will be completed within 72 hours from receipt of request.

CVS Caremark has established an Inter-Rater Reliability process for monitoring the consistent application of clinical guidelines across utilization review decisions.

Plan/Issuer Response – In Operation:

Testing Methodology

The processed input drug coverage extract file was analyzed as follows:

- Drugs with formulary UM NQTLs were grouped into MH, SUD and MED/SURG drug types, counted, and totals were used to calculate the percentages on each type.
- Drugs with formulary UM NQTLs in the MH/SUD and MED/SURG types were grouped by therapeutic class, counted, and the totals were used to calculate percentages on each class.
- Samples of drug classes for chronic MED/SURG conditions were chosen as comparators. (See Appendix 3)
- Comparisons were performed at the drug class level, by count and percent, and by the factors considered and applied in each of the classes within each of the MH/SUD and MED/SURG drug types.

In Operation Results

Step Therapy Drug Type Results

AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Count	2,809	609	120
ST Count	78	23	0
ST Percent	**2.8%**	**3.8%**	**0.0%**

Step Therapy Drug Class Comparison Results

AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

MED/SURG Drug Class Comparators	Total Count	ST Count	ST Percent
DIABETES	99	38	38%
ANTIHYPERTENSIVES	153	0	0%
ANTIHYPERLIPIDEMICS	57	1	2%
ASTHMA/COPD	72	0	0%
OPIOIDS	97	0	0%
ANTI-INFLAMMATORY	77	0	0%
MIGRAINE	36	8	22%

MH Drug Classes	Total Count	ST Count	ST Percent
ADHD	107	0	0%
ANXIETY	51	0	0%
BIPOLAR/SCHIZOPHRENIA	145	6	4%
DEPRESSION	139	8	6%
ENDOCRINE REGULATION	40	0	0%
NEUROCOGNITIVE DISORDERS	91	9	10%
SLEEP-WAKE DISORDERS	36	0	0%

ANTICOAGULANTS	49	0	0%
OPHTHALMICS	84	1	1%
ACNE	30	0	0%

SUD Drug Classes	Total Count	ST Count	ST Percent
ALCOHOL USE DISORDER (AUD)	55	0	0%
OPIOID USE DISORDER (OUD)	40	0	0%
TOBACCO USE DISORDER (TUD)	25	0	0%

In Operation Results for Prescription Drug Utilization Management Review Process

AETNA of ILLINOIS - Aetna Exchange Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Requests	702	81	0
Total Approvals	487	68	0
Total Denials	215	13	0
Approval Percent	69.4%	84.0%	0%
Denial Percent	30.6%	16.0%	0%

COMPARABILITY ANALYSIS
In operation, the step therapy approval rate of 84.0% for MH drug requests is higher than the step therapy approval rate of 69.4% for Med/Surg drug requests.
There were no requests for step therapy for SUD drugs.

INTERRATER RELIABILITY REVIEWS
To evaluate the quality, accuracy, and consistency among clinical pharmacists' reviews of Prior Authorizations, Aetna's delegated UR agent, Caremark, conducts Inter-Rater Reliability reviews on random samples of prior authorization cases following methodology set forth by National Committee for Quality Assurance (NCQA).

Results
During the audit period of July 1, 2023, through June 30, 2024, a total of 215 prior authorization determinations were reviewed consistent with the Caremark Prior Authorization Inter-Rater Reliability (IRR) Process policy[1]. Cases reviewed during this audit period resulted in an agreement rate of 99.5%. The results demonstrate a consistent adherence to prior authorization policies and clinical decision making with respect to prior authorization criteria and determinations.

Criteria for the IRR process is selected without regard to the specific therapeutic classification of drug. The sample selected may include mental health / substance use disorder and medical surgical drugs. There is no separate process to target MH/SUD or MS for review.

Stringency of coverage requests reviews analysis:

To demonstrate the in-operations parity with respect to reviewer activities evaluating Prior Authorization and Step Therapy coverage determinations, Aetna audited a random sample

of denied cases across the MH/SUD and Med Surg. classification of drugs. Quality Assurance auditors utilized the Clinical Adjudication System and other supporting systems to review the coverage determination sample. For each question described in the methodology below the auditor reviewed the user's work to determine whether the initial review correctly followed the department's expectations regarding specific tasks related to the coverage request and process review.

The methodology and results of that analysis are described below.

Methodology

- A random sample of 20 coverage determination cases were selected for all formularies.
- Prior authorization 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* Med/Surg 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 indicated to treated either a MH/SUD or Med Surg condition.
- The universe of eligible Med/Surg cases for comparison to MH cases included requests for analgesics, anti-diabetic medications, ophthalmic agents, migraine products, anti-asthmatic agents and dermatological products.

- Following 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?
    - Was the decision turn-around time in compliance with policy requirements?
- Each case was subject to an audit by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.
- The selection criteria and sample composition was as follows:

Drug Classification	Utilization Management classification	Count
MH*	Prior Authorization	5
MH*	Step Therapy	5
Medical Surgical	Prior Authorization	5
Medical Surgical	Step Therapy	5

*No Prior Authorizations or Step Therapy denials were identified for SUD drugs

Results

The results of the audit were that all 20 audit samples met expectations and when MH cases were compared to Med/Surg 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 correct criteria was selected and used, the criteria questions were answered accurately and completely, 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 with the exception of one case involving a standard review for a Med/Surg drug.

The review of the cases demonstrated that the process for reviews was consistent across

all prior authorization requests for Mental Health and MED/SURG cases. In every case, the health care professional responsible for the determination was a physician. There were no peer-to-peer discussions requested in any of the samples reviewed.

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Testing of the formulary step therapy NQTL shows that overall, it is applied to a lower percentage of MH drugs and zero SUD drugs compared to MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of UM NQTLs revealed that the factors and the sources are not used more stringently for MH/SUD compared to MED/SURG drugs and justify the current application of UM NQTLs to some of the drugs on this formulary.

In Conclusion for the Prescription Drug Utilization Management Review Process and taking into consideration the approval and denial rates for prior authorization and step therapy the ongoing interrater reviews and the in-operation audits conducted on MH and MED/SURG drugs, the results from in-operation review demonstrated that the prior authorization process is being conducted and executed uniformly consistent with the policies and procedures and that the policies were not applied more stringently to reviews involving MH drugs as compared to reviews for Med/Surg drugs.

The information provided in steps 1-4 is sufficient to conclude compliance with MH Parity requirements.

This analysis has demonstrated that the application of prior authorization as a NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained. Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:
X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:
X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports. The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Step Therapy – Standard Opt Out Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definitions

Generally based on medical practice and other clinical standards, utilization management (UM) tools are used primarily to control utilization and include the following:

Step therapy (ST) requires that preferred drugs be tried first before covering another non-preferred drug.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Cost-effectiveness	Cost-effectiveness

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia

MED/SURG	MH/SUD
Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement

Applicable Sources and Evidentiary Standards for Prescription Drug Utilization Management Review Process

MED/SURG	MH/SUD
CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)	CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)
[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P]	[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P
[CVS CAREMARK IRR P&P] Document ID: PAR-0010]	[CVS CAREMARK IRR P&P; Document ID: PAR-0010]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Methodology

Comparative analysis of the application of factors as written was performed via a review of:

- utilization management policies and procedures
- samples of drug information documents, therapeutic class reviews and prior authorization criteria
- committee's policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the application of a PA, ST and/or QL on a drug to confirm that its use will follow the evidence-based drug uses. PA is applied when evidence-based drug use indicates that a diagnosis requires monitoring of the patient response, or additional supportive therapy is appropriate. ST is applied when appropriate alternatives are available. QL is applied when there is evidence that long-term and/or
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	unsupervised use of a drug may compromise the patient's safety.
	External clinical experts	
	Similar drugs	
Cost-effectiveness	Similar drugs	Sources inform whether it is cost-effective to use PA, ST and/or QL. Similar drugs that have PA, ST and/or QL provide clinical context for the application of the limitation and consistency. Utilization trend reports indicate whether it is cost-effective to operationalize the PA, ST and/or QL.
	Utilization trend reports	
	Applicable manufacturer agreement	

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The UM Clinical Development team drafts UM NQTL requirements that include coverage for use supported by evidence-based medicine and standard of care sources.
- The Formulary Review Committee (FRC), meets regularly to discuss and review drug information and makes recommendations for prior authorization for the P&T Committee's review and approval.
- Standard UM NQTLs are reviewed internally by a CVS Caremark Medical Director, and externally by external clinical experts coordinated through the Clinical Program Oversight (CPO) review process.
- The P&T Committee reviews and approves the UM NQTLs.

No separate policies or procedures exist with respect to UM NQTLs for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; both drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to MED/SURG drugs. The meeting minutes show that these experts evaluate and consider the factors for applying UM NQTLs in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

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 the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. Age restrictions are applied to MH/SUD or MED/SURG drugs if clinical evidence indicates a drug is potentially harmful or not effective in a population that can be defined by age, and these restrictions were found in the sample prior authorization criteria reviewed. The P&T Committee members use these drug information documents,

therapeutic class reviews and presentations to make informed decisions and vote on recommendations using the same process and equally weighing applicable factors and sources for formulary UM NQTLs considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

As Written Comparative Analysis for Prescription Drug Utilization Management Review Process

The CVS Caremark utilization management review program is administered by the CVS Caremark Clinical Operations unit. Consistent with CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois), 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 MED/SURG conditions or diseases.
Providers can submit coverage requests subject to utilization management electronically, by phone, fax, or in writing. CVS Caremark utilizes and accepts the Illinois Uniform Electronic Prior Authorization form which is available online at www.caremark.com. Requests are accepted 24 hours a day.
Representatives may be utilized to input data from coverage review requests into CVS Caremark's Clinical Administration System (CAS) system. An automated algorithm will determine if such data conforms to pre-established criteria for coverage. If the algorithm determines that the data conforms to the plan criteria for coverage, an approval letter will be systematically generated. If the data does not conform to the criteria for coverage, the request will be forwarded to a pharmacist for further review. In addition, if any data on the PA request is unclear, the request will be forwarded to a licensed practical nurse or pharmacist for further review. Reviews may also be performed by licensed pharmacists who are in good standing, if required, by the state in which they work.
Non-clinical or administrative denials are completed by a representative under the supervision of a licensed health care professional. Clinical denials are rendered by a board-certified physician reviewer who possesses a current and valid nonrestricted license in any United States jurisdiction.
The Clinical Operations unit will make a determination and give written notice to the provider and plan member regarding a determination involving prior authorizations or step therapy exception requests as fast as the plan member's condition requires and following the following timeframes:

a. Urgent pre-service reviews will be completed within 24 hours from receipt of request.

b. Non-urgent pre-service Reviews will be completed within 72 hours from receipt of request.

CVS Caremark has established an Inter-Rater Reliability process for monitoring the consistent application of clinical guidelines across utilization review decisions.

Plan/Issuer Response – In Operation:

Testing Methodology

The processed input drug coverage extract file was analyzed as follows:

- Drugs with formulary UM NQTLs were grouped into MH, SUD and MED/SURG drug types, counted, and totals were used to calculate the percentages on each type.
- Drugs with formulary UM NQTLs in the MH/SUD and MED/SURG types were grouped by therapeutic class, counted, and the totals were used to calculate percentages on each class.
- Samples of drug classes for chronic MED/SURG conditions were chosen as comparators. (See Appendix 3)
- Comparisons were performed at the drug class level, by count and percent, and by the factors considered and applied in each of the classes within each of the MH/SUD and MED/SURG drug types.

In Operation Results

Step Therapy Drug Type Results

AETNA of ILLINOIS - Standard Opt Out Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Count	4,474	867	123
ST Count	38	39	0
ST Percent	**0.8%**	**4.5%**	**0.0%**

Step Therapy Drug Class Comparison Results

AETNA of ILLINOIS - Standard Opt Out Formulary - 2024

MED/SURG Drug Class Comparators	Total Count	ST Count	ST Percent
DIABETES	227	0	0%
ANTIHYPERTENSIVES	179	4	2%
ANTIHYPERLIPIDEMICS	77	12	16%
ASTHMA/COPD	109	0	0%
OPIOIDS	212	0	0%
ANTI-INFLAMMATORY	103	0	0%
MIGRAINE	49	3	6%
ANTICOAGULANTS	62	0	0%

MH Drug Classes	Total Count	ST Count	ST Percent
ADHD	169	0	0%
ANXIETY	64	0	0%
BIPOLAR/SCHIZOPHRENIA	223	21	9%
DEPRESSION	166	8	5%
ENDOCRINE REGULATION	74	0	0%
NEUROCOGNITIVE DISORDERS	120	0	0%
SLEEP-WAKE DISORDERS	51	10	20%
SUD Drug Classes	**Total Count**	**ST Count**	**ST Percent**

OPHTHALMICS	134	4	3%	ALCOHOL USE DISORDER (AUD)	58	0	0%
ACNE	60	2	3%	OPIOID USE DISORDER (OUD)	40	0	0%
				TOBACCO USE DISORDER (TUD)	25	0	0%

In Operation Results for Prescription Drug Utilization Management Review Process

Approval/Denial Rates – Step Therapy Exceptions

AETNA of ILLINOIS - Aetna Standard Opt Out Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Requests	5	0	0
Total Approvals	5	0	0
Total Denials	0	0	0
Approval Percent	100%	0%	0%
Denial Percent	0%	0%	0%

COMPARABILITY ANALYSIS
There were no requests for step therapy for MH or SUD Drugs.

INTERRATER RELIABILITY REVIEWS
To evaluate the quality, accuracy, and consistency among clinical pharmacists' reviews of Prior Authorizations, Aetna's delegated UR agent, Caremark, conducts Inter-Rater Reliability reviews on random samples of prior authorization cases following methodology set forth by National Committee for Quality Assurance (NCQA).

Results
During the audit period of July 1, 2023, through June 30, 2024, a total of 215 prior authorization determinations were reviewed consistent with the Caremark Prior Authorization Inter-Rater Reliability (IRR) Process policy[1]. Cases reviewed during this audit period resulted in an agreement rate of 99.5%. The results demonstrate a consistent adherence to prior authorization policies and clinical decision making with respect to prior authorization criteria and determinations.

Criteria for the IRR process is selected without regard to the specific therapeutic classification of drug. The sample selected may include mental health / substance use disorder and medical surgical drugs. There is no separate process to target MH/SUD or MS for review.

Stringency of coverage requests reviews analysis:

To demonstrate the in-operations parity with respect to reviewer activities evaluating Prior Authorization and Step Therapy coverage determinations, Aetna audited a random sample of denied cases across the MH/SUD and Med Surg. classification of drugs. Quality Assurance auditors utilized the Clinical Adjudication System and other supporting systems to review the coverage determination sample. For each question described in the methodology below the auditor reviewed the user's work to determine whether the initial review correctly followed the department's expectations regarding specific tasks related to the coverage request and process review.

The methodology and results of that analysis are described below.

Methodology

- A random sample of 20 coverage determination cases were selected for all formularies.
- Prior authorization 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* Med/Surg 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 indicated to treated either a MH/SUD or Med Surg condition.
- The universe of eligible Med/Surg cases for comparison to MH cases included requests for analgesics, anti-diabetic medications, ophthalmic agents, migraine products, anti-asthmatic agents and dermatological products.

- Following 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?
    - Was the decision turn-around time in compliance with policy requirements?
- Each case was subject to an audit by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.
- The selection criteria and sample composition was as follows:

Drug Classification	Utilization Management classification	Count
MH*	Prior Authorization	5
MH*	Step Therapy	5
Medical Surgical	Prior Authorization	5
Medical Surgical	Step Therapy	5

*No Prior Authorizations or Step Therapy denials were identified for SUD drugs

Results

The results of the audit were that all 20 audit samples met expectations and when MH cases were compared to Med/Surg 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 correct criteria was selected and used, the criteria questions were answered accurately and completely, 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 with the exception of one case involving a standard review for a

Med/Surg drug.

The review of the cases demonstrated that the process for reviews was consistent across all prior authorization requests for Mental Health and MED/SURG cases. In every case, the health care professional responsible for the determination was a physician. There were no peer-to-peer discussions requested in any of the samples reviewed.

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Testing of the formulary step therapy NQTL shows that overall, it is applied to a lower percentage of MH drugs and zero SUD drugs compared to MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of UM NQTLs revealed that the factors and the sources are not used more stringently for MH/SUD compared to MED/SURG drugs and justify the current application of UM NQTLs to some of the drugs on this formulary.

In Conclusion for the Prescription Drug Utilization Management Review Process and taking into consideration the approval and denial rates for prior authorization and step therapy the ongoing interrater reviews and the in-operation audits conducted on MH and MED/SURG drugs, the results from in-operation review demonstrated that the prior authorization process is being conducted and executed uniformly consistent with the policies and procedures and that the policies were not applied more stringently to reviews involving MH

drugs as compared to reviews for Med/Surg drugs.
The information provided in steps 1-4 is sufficient to conclude compliance with MH Parity requirements.

This analysis has demonstrated that the application of prior authorization as a NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions.

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained. Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:

X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:

X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports. The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization

Nonquantitative Treatment Limitation (NQTL) Submission Form

Instructions: This NQTL reporting submission form includes the required five elements as specified by 42 U.S.C. Section 300gg-26(a)(8)(A); 29 U.S.C. Section 1185a(a)(8)(A); and 26 U.S.C. Section 9812(a)(8)(A). Plans and issuers (or a department) can choose to submit a different form for each classification of benefits (recommended approach) or duplicate the prompts below for each classification of benefits. It is not recommended that a plan or issuer submit multiple NQTLs in the same document.

Step Therapy – Advanced Control Formulary

Benefit Classifications/Subclassifications

- **Prescription Drug**

Step 1:

Specify the specific Plan or coverage terms or other relevant terms regarding the NQTL, that apply to such Plan or coverage, and provide a description of all mental health or substance use disorder and medical or surgical benefits to which the NQTL applies or for which it does not apply.

FAQ 45 Guidance: The FAQ 45 (Q2, #'s 1 and 2) guidance stipulate that a sufficient analysis should include:

A clear description of the specific NQTL, plan terms, and policies at issue; and

Identification of the specific mental health or substance use disorder and medical or surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as mental health or substance use disorder and which are treated as medical or surgical.

Plan/Issuer Response:

Definitions

Generally based on medical practice and other clinical standards, utilization management (UM) tools are used primarily to control utilization and include the following:

Step therapy (ST) requires that preferred drugs be tried first before covering another non-preferred drug.

Step 2:

Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q2, #3) guidance stipulates that a sufficient analysis includes:

Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both mental health or substance use disorder benefits and medical or surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.

Plan/Issuer Response:

Factors

Definition of Factors (see Appendix 1)

MED/SURG	MH/SUD
Evidence-based drug uses	Evidence-based drug uses
Cost-effectiveness	Cost-effectiveness

Step 3:

Provide the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 (Q 2, # 4) guidance stipulates that a sufficient response includes:

To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

The FAQ 45 guidance (Q 3, # 5) states that the following is insufficient:

Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Plan/Issuer Response:

Applicable Sources and Evidentiary Standards

MED/SURG	MH/SUD
US Food and Drug Administration labeling	US Food and Drug Administration labeling
Centers for Medicare & Medicaid Services accepted drug compendia	Centers for Medicare & Medicaid Services accepted drug compendia

MED/SURG	MH/SUD

Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies
External clinical experts	External clinical experts
Similar drugs	Similar drugs
Utilization trend reports	Utilization trend reports
Applicable manufacturer agreement	Applicable manufacturer agreement

Applicable Sources and Evidentiary Standards for Prescription Drug Utilization Management Review Process

MED/SURG	MH/SUD
CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)	CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois)
[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P]	[CVS CAREMARK QUALITY ASSURANCE PROCESS P&P
[CVS CAREMARK IRR P&P] Document ID: PAR-0010]	[CVS CAREMARK IRR P&P; Document ID: PAR-0010]

Step 4:

Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to mental health or substance use disorder benefits, **as written and in operation**, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits.

FAQ 45 Guidance: The FAQ 45 guidance states that the following is necessary for a sufficient response:

(Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between mental health or substance use disorder and medical or

surgical benefits and, if so, describe the process and factors used for establishing that variation.

(Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).

(Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both mental health or substance use disorder and medical or surgical benefits.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.

(Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

(Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.

(Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Plan/Issuer Response – As Written:

Methodology

Comparative analysis of the application of factors as written was performed via a review of:

- utilization management policies and procedures
- samples of drug information documents, therapeutic class reviews and prior authorization criteria
- committee's policies and procedures and meeting minutes

As Written Findings

Factor†	Sources Relied Upon	How Sources Are Used
Evidence-based drug uses	US Food and Drug Administration labeling	Sources inform the application of a PA, ST and/or QL on a drug to confirm that its use will follow the evidence-based drug uses. PA is applied when evidence-based drug use indicates that a diagnosis requires monitoring of the patient response, or additional supportive therapy is appropriate. ST is applied when appropriate alternatives are available. QL is applied when there is evidence that long-term and/or
	Centers for Medicare & Medicaid Services accepted drug compendia	

	Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies	unsupervised use of a drug may compromise the patient's safety.
	External clinical experts	
	Similar drugs	
Cost-effectiveness	Similar drugs	Sources inform whether it is cost-effective to use PA, ST and/or QL. Similar drugs that have PA, ST and/or QL provide clinical context for the application of the limitation and consistency. Utilization trend reports indicate whether it is cost-effective to operationalize the PA, ST and/or QL.
	Utilization trend reports	
	Applicable manufacturer agreement	

†All factors are considered during decision-making, and no factor is used in isolation.

Process

The following teams and committees within the CVS Caremark Medical Affairs department play an integral role in the utilization management development process and support the independent Caremark National Pharmacy and Therapeutics (P&T) Committee:

- The UM Clinical Development team drafts UM NQTL requirements that include coverage for use supported by evidence-based medicine and standard of care sources.
- The Formulary Review Committee (FRC), meets regularly to discuss and review drug information and makes recommendations for prior authorization for the P&T Committee's review and approval.
- Standard UM NQTLs are reviewed internally by a CVS Caremark Medical Director, and externally by external clinical experts coordinated through the Clinical Program Oversight (CPO) review process.
- The P&T Committee reviews and approves the UM NQTLs.

No separate policies or procedures exist with respect to UM NQTLs for MH/SUD drugs as compared to MED/SURG drugs. Additionally, no separate meetings occur to vote on decisions about MH/SUD drugs compared to MED/SURG drugs; both drugs are considered in the same meetings without regard to whether they treat MH/SUD or MED/SURG conditions.

The policies and procedures show that personnel and committee members follow a process that is no different for MH/SUD compared to MED/SURG drugs. The meeting minutes show that these experts evaluate and consider the factors for applying UM NQTLs in the same manner, regardless of whether a drug is used to treat a MH/SUD or MED/SURG condition or disease.

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 the policies. The sources are cited in the drug information documents and therapeutic class review references, and their use is consistent with the policies and procedures. Age restrictions are applied to MH/SUD or MED/SURG drugs if clinical evidence indicates a drug is potentially harmful or not effective in a population that can be defined by age, and these restrictions were found in the sample prior authorization criteria reviewed. The P&T Committee members use these drug information documents,

therapeutic class reviews and presentations to make informed decisions and vote on recommendations using the same process and equally weighing applicable factors and sources for formulary UM NQTLs considerations.

The FRC and P&T Committee members have different expertise and credentials, but there is no difference in level of expertise required to participate as a voting member for MH/SUD compared to MED/SURG conditions. The members' participation is not based on whether a drug being considered is used to treat MH/SUD or MED/SURG conditions or diseases.

As Written Comparative Analysis for Prescription Drug Utilization Management Review Process

The CVS Caremark utilization management review program is administered by the CVS Caremark Clinical Operations unit. Consistent with CVS Caremark Policy and Procedure - DOC-075836, Prior Authorization Process (Illinois), 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 MED/SURG conditions or diseases.
Providers can submit coverage requests subject to utilization management electronically, by phone, fax, or in writing. CVS Caremark utilizes and accepts the Illinois Uniform Electronic Prior Authorization form which is available online at www.caremark.com. Requests are accepted 24 hours a day.
Representatives may be utilized to input data from coverage review requests into CVS Caremark's Clinical Administration System (CAS) system. An automated algorithm will determine if such data conforms to pre-established criteria for coverage. If the algorithm determines that the data conforms to the plan criteria for coverage, an approval letter will be systematically generated. If the data does not conform to the criteria for coverage, the request will be forwarded to a pharmacist for further review. In addition, if any data on the PA request is unclear, the request will be forwarded to a licensed practical nurse or pharmacist for further review. Reviews may also be performed by licensed pharmacists who are in good standing, if required, by the state in which they work.
Non-clinical or administrative denials are completed by a representative under the supervision of a licensed health care professional. Clinical denials are rendered by a board-certified physician reviewer who possesses a current and valid nonrestricted license in any United States jurisdiction.
The Clinical Operations unit will make a determination and give written notice to the provider and plan member regarding a determination involving prior authorizations or step therapy exception requests as fast as the plan member's condition requires and following the following timeframes:

a. Urgent pre-service reviews will be completed within 24 hours from receipt of request.

b. Non-urgent pre-service Reviews will be completed within 72 hours from receipt of request.

CVS Caremark has established an Inter-Rater Reliability process for monitoring the consistent application of clinical guidelines across utilization review decisions.

Plan/Issuer Response – In Operation:

Testing Methodology

The processed input drug coverage extract file was analyzed as follows:

- Drugs with formulary UM NQTLs were grouped into MH, SUD and MED/SURG drug types, counted, and totals were used to calculate the percentages on each type.
- Drugs with formulary UM NQTLs in the MH/SUD and MED/SURG types were grouped by therapeutic class, counted, and the totals were used to calculate percentages on each class.
- Samples of drug classes for chronic MED/SURG conditions were chosen as comparators. (See Appendix 3)
- Comparisons were performed at the drug class level, by count and percent, and by the factors considered and applied in each of the classes within each of the MH/SUD and MED/SURG drug types.

In Operation Results

Step Therapy Drug Type Results

AETNA of ILLINOIS - Advanced Control Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Count	3,776	749	122
ST Count	98	10	0
ST Percent	**2.6%**	**1.3%**	**0.0%**

Step Therapy Drug Class Comparison Results

AETNA of ILLINOIS - Advanced Control Formulary - 2024

MED/SURG Drug Class Comparators	Total Count	ST Count	ST Percent
DIABETES	128	35	27%
ANTIHYPERTENSIVES	162	1	1%
ANTIHYPERLIPIDEMICS	62	0	0%
ASTHMA/COPD	73	0	0%
OPIOIDS	137	0	0%
ANTI-INFLAMMATORY	95	0	0%
MIGRAINE	55	26	47%

MH Drug Classes	Total Count	ST Count	ST Percent
ADHD	130	1	1%
ANXIETY	64	0	0%
BIPOLAR/SCHIZOPHRENIA	197	0	0%
DEPRESSION	140	3	2%
ENDOCRINE REGULATION	60	0	0%
NEUROCOGNITIVE DISORDERS	116	0	0%
SLEEP-WAKE DISORDERS	42	6	14%

ANTICOAGULANTS	40	0	0%
OPHTHALMICS	91	0	0%
ACNE	49	3	6%

SUD Drug Classes	Total Count	ST Count	ST Percent
ALCOHOL USE DISORDER (AUD)	57	0	0%
OPIOID USE DISORDER (OUD)	40	0	0%
TOBACCO USE DISORDER (TUD)	25	0	0%

In Operation Results for Prescription Drug Utilization Management Review Process

Approval/Denial Rates – Step Therapy Exceptions

AETNA of ILLINOIS - Aetna Advanced Control Formulary - 2024

Drug Type	MED/SURG	MH	SUD
Total Requests	1247	97	0
Total Approvals	965	82	0
Total Denials	282	15	0
Approval Percent	77.4%	84.5%	0%
Denial Percent	22.6%	15.5%	0%

COMPARABILITY ANALYSIS
In operation, the step therapy approval rate of 84.5% for MH drug requests is higher than the step therapy approval rate of 77.4% for Med/Surg drug requests.
There were no requests for step therapy for SUD drugs.

INTERRATER RELIABILITY REVIEWS
To evaluate the quality, accuracy, and consistency among clinical pharmacists' reviews of Prior Authorizations, Aetna's delegated UR agent, Caremark, conducts Inter-Rater Reliability reviews on random samples of prior authorization cases following methodology set forth by National Committee for Quality Assurance (NCQA).

Results
During the audit period of July 1, 2023, through June 30, 2024, a total of 215 prior authorization determinations were reviewed consistent with the Caremark Prior Authorization Inter-Rater Reliability (IRR) Process policy[1]. Cases reviewed during this audit period resulted in an agreement rate of 99.5%. The results demonstrate a consistent adherence to prior authorization policies and clinical decision making with respect to prior authorization criteria and determinations.

Criteria for the IRR process is selected without regard to the specific therapeutic classification of drug. The sample selected may include mental health / substance use disorder and medical surgical drugs. There is no separate process to target MH/SUD or MS for review.

Stringency of coverage requests reviews analysis:

To demonstrate the in-operations parity with respect to reviewer activities evaluating Prior Authorization and Step Therapy coverage determinations, Aetna audited a random sample of denied cases across the MH/SUD and Med Surg. classification of drugs. Quality Assurance auditors utilized the Clinical Adjudication System and other supporting systems to review the coverage determination sample. For each question described in the methodology below the auditor reviewed the user's work to determine whether the initial review correctly followed the department's expectations regarding specific tasks related to the coverage request and process review.

The methodology and results of that analysis are described below.

Methodology

- A random sample of 20 coverage determination cases were selected for all formularies.
- Prior authorization 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* Med/Surg 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 indicated to treated either a MH/SUD or Med Surg condition.
- The universe of eligible Med/Surg cases for comparison to MH cases included requests for analgesics, anti-diabetic medications, ophthalmic agents, migraine products, anti-asthmatic agents and dermatological products.

- Following 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?
    - Was the decision turn-around time in compliance with policy requirements?
- Each case was subject to an audit by a clinical pharmacist, specifically evaluating the compliance with questions outlined above.
- The selection criteria and sample composition was as follows:

Drug Classification	Utilization Management classification	Count
MH*	Prior Authorization	5
MH*	Step Therapy	5
Medical Surgical	Prior Authorization	5
Medical Surgical	Step Therapy	5

*No Prior Authorizations or Step Therapy denials were identified for SUD drugs

Results

The results of the audit were that all 20 audit samples met expectations and when MH cases were compared to Med/Surg 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 correct criteria was selected and used, the criteria questions were answered accurately and completely, 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 with the exception of one case involving a standard review for a Med/Surg drug.

The review of the cases demonstrated that the process for reviews was consistent across all prior authorization requests for Mental Health and MED/SURG cases. In every case, the health care professional responsible for the determination was a physician. There were no peer-to-peer discussions requested in any of the samples reviewed.

Step 5:

The specific findings and conclusions reached by the Plan or issuer with respect to the health insurance coverage, including any results of the analyses described in the previous steps that indicate that the Plan or issuer is or is not in compliance with the MHPAEA NQTL requirements.

FAQ 45 Guidance: The FAQ 45 guidance states that a sufficient response should include:

(Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

The FAQ 45 guidance states that the following constitutes an insufficient response:

(Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Plan/Issuer Conclusion:

Testing of the formulary step therapy NQTL shows that overall, it is applied to a lower percentage of MH drugs and zero SUD drugs compared to MED/SURG.

As written, a review of the policies and procedures, minutes, and drug information documents and therapeutic class reviews revealed that the same factors are used, in the same manner, relying on the same sources that are specific to each drug or drug class, and have the same level of evidence. The personnel involved and their credentials do not differ based on whether a drug considered is MH/SUD or MED/SURG.

In operation, analysis and testing of UM NQTLs revealed that the factors and the sources are not used more stringently for MH/SUD compared to MED/SURG drugs and justify the current application of UM NQTLs to some of the drugs on this formulary.

In Conclusion for the Prescription Drug Utilization Management Review Process and taking into consideration the approval and denial rates for prior authorization and step therapy the ongoing interrater reviews and the in-operation audits conducted on MH and MED/SURG

drugs, the results from in-operation review demonstrated that the prior authorization process is being conducted and executed uniformly consistent with the policies and procedures and that the policies were not applied more stringently to reviews involving MH drugs as compared to reviews for Med/Surg drugs.
The information provided in steps 1-4 is sufficient to conclude compliance with MH Parity requirements.

This analysis has demonstrated that the application of prior authorization as a NQTL, the factors, evidentiary standards, sources, processes, identified above, both as written and in operation, are not applied more stringently to drugs used for MH/SUD conditions than to drugs used for MED/SURG conditions.

Appendix 1 Definition of Factors

Cost-effectiveness – When multiple drugs exist to treat a given condition, the drugs that are equally efficacious and are less costly are placed in a preferred position to provide more cost-effective therapy options. These drugs are typically a generic equivalent, biosimilar or a therapeutic alternative. A generic equivalent or biosimilar drug are defined consistent with the definition of those terms by the US Food and Drug Administration; a therapeutic alternative means it is a different chemical agent in the same pharmacological or therapeutic class and has a similar therapeutic effect. These existing multiple drugs can include a drug with multiple dosage forms available. A dosage form is the physical form in which a drug is manufactured or administered. Examples of dosage forms include tablets, capsules, powders, oral disintegrating tablets and oral and injectable solutions. A drug may be available in multiple dosage forms, with vastly different costs which may or may not offer a clinical advantage. More cost-effective treatment options may be available and covered in a preferred position, may not require a prior authorization or step therapy and would be a generic equivalent, biosimilar or a therapeutic alternative. The plan sponsor cost is the lowest net cost option for a generic equivalent, biosimilar, or brand-name drug being considered.

Drug pipeline – In the pharmaceutical industry, drugs in development are referred to as being “in the pipeline”. Monitoring late-stage development of new brands, generics, biosimilars, supplemental indications, or over the counter switches, informs the potential future availability of new therapies.

Evidence-based drug uses – The generally accepted safe and efficacious use of a drug for a particular illness, disease, or condition within the intended treatment population; the generally accepted sequential drug use (e.g., initial [first line] therapy, second line therapy), or concurrent drug use. Safer and more efficacious drugs and/or first line therapies are typically placed in preferred positions. It includes the physician practice of prescribing a drug for a purpose other than one of the indications for which the product is approved by the US Food and Drug Administration. It includes consideration for patient safety and whether there is evidence of harm or unknown long-term safety, and/or evidence that long-term and/or unsupervised use of a drug may compromise the patient’s safety. Evidence-based drug uses may require a laboratory value or test, or may indicate a restriction to a population with certain specific characteristics or attributes (e.g., age, gender, diagnoses, comorbidities, site of care, treatment-naïve/experienced). Evidence-based drug uses may signal the potential 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. During treatment, evidence-based drug use may warrant the confirmation that a patient is responding to therapy via patient monitoring. Additionally, evidence-based drug use may require additional treatment-supportive therapies (e.g., behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies)**.**

Regulatory requirements (as applicable) – Federal/state regulations dictate how certain drugs should be covered on the formulary.

Specialty drug status – Specialty drugs are used for difficult to treat chronic conditions, requiring close monitoring and/or education of the patient. These high-cost drugs may require patient-specific dosing, medical devices, special handling and delivery, and/or limited distribution by a manufacturer; these drugs may need to be dispensed from a specialty pharmacy.

Appendix 2 CVS Caremark Personnel
Titles, Credentials and Committees Composition

The CVS Caremark Medical Affairs Department led by the Caremark Chief Medical Officer has primary oversight responsibility for Pharmacy Benefit NQTL design and application. Within the Medical Affairs Department, multiple units manage different aspects of the NQTL strategy.

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 **Utilization Management Clinical Development Department** drafts UM criteria.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Registered Nurse
Lead Director, Pharmacist
Sr Managers, Nurse, and Pharmacists
Clinical Pharmacists
Analysts

The **Clinical Program Oversight (CPO) Department** coordinates the review of UM criteria by External clinical expert consultants.

Job Title - Credential
VP Medical Affairs, Pharmacist
Executive Director, Pharmacist
Sr Manager, Pharmacist
Clinical Pharmacists
Analyst
External Clinical Experts

The **Medical Directors** review UM criteria.

Job Title - Credential
VP Medical Affairs, MD
Exec Directors, Medical Director, MD
Medical Directors, MD
Medical Directors, DO

The **Formulary Review Committee (FRC)** makes business recommendations. It 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

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, approves the criteria.

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	

Appendix 3 Methodology Details

Parity regulations do not dictate a methodology for comparative analyses, but guidance states that data presented as evidence of a comparable application of numerical inputs, underlying methodologies, and calculations behind the results should be explained.
Following this guidance, this appendix further explains the methodology used for this analysis.

Calculations

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

To calculate the percent of drug type having each UM, the formula used is (X/Y)*100, where:
X = the count of drugs having each UM
Y = the total count of that drug type in the formulary

To calculate the percent of drug type having each UM in each drug class, the formula used is (X/Y)*100, where:
X = count of drugs having each UM in each drug class
Y = the total count of that drug type in the same drug class in the formulary

UM Comparator Classes Selection Methodology

Because the formulary includes hundreds of MED/SURG drug classes, the comparator classes were narrowed using prescription claims data reports. The drug classes identified in the MED/SURG type in each UM comparator table, was narrowed to those that are used by a population with chronic conditions, have greater than 100,000 member utilizers and generate greater than $40 million in cost. The resulting representative comparator classes are as follows:

MED/SURG Comparator Classes	
Acne Products	Anti-inflammatory
Anticoagulants	Asthma / COPD*
Antidiabetics	Migraine Products
Antihyperlipidemics	Ophthalmic Agents
Antihypertensives	Opioids†

*COPD: chronic obstructive pulmonary disease
†Class generates lower cost but has high utilization