MHPAEA Summary Form

Under a federal law called the Mental Health Parity and Addiction Equity Act (MHPAEA), Aetna Life Insurance Company must make sure that there is "parity" between mental health and substance use disorder benefits, and medical and surgical benefits. This generally means that financial requirements and treatment limitations applied to mental health or substance use disorder benefits cannot be more restrictive than the financial requirements and treatment limitations applied to medical and surgical benefits. The types of limits covered by parity protections include:

- Financial requirements—such as deductibles, copayments, coinsurance, and out-of-pocket limits; and
- Treatment limitations—such as limits on the number of days or visits covered, or other limits on the scope or duration of treatment (for example, being required to get prior authorization).

Aetna Health Insurance Company has performed an analysis of mental health parity as required by Maryland law and has submitted the required report to the State of Maryland. Below is a summary of that report.

If you have any questions on this summary, please contact **MHPGeneralInquiries@aetna.com**.

If you have questions on your specific health plan, please call the member services number on your ID card.

Overview:

We have identified the five health benefit plans with the highest enrollment for each product we offer in the individual, small, and large group markets, as applicable. These plans contain items called Non-Quantitative Treatment Limitations (NQTLs) that put limits on benefits paid. What these NQTLs are and how the health plans achieve parity are discussed below.

1. **Definition of Medical Necessity**

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits	MH/SUD Benefits
Medically necessary means healthcare services provided for the purpose of preventing, evaluating, diagnosing or treating a sickness, injury, mental Illness, substance use disorder, condition, disease or its symptoms that are all of the following as determined by the Claims Administrator or its designee, within the Claims Administrator's sole discretion. The services must be: • 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 sickness, injury, mental illness, substance use disorder disease or its symptoms; • not mainly for your convenience or that of your doctor or other health care provider; and • not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms. *Generally Accepted Standards of Medical Practice* are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes.	Medically necessary means healthcare services provided for the purpose of preventing, evaluating, diagnosing or treating a sickness, injury, mental Illness, substance use disorder, condition, disease or its symptoms that are all of the following as determined by the Claims Administrator, within the Claims Administrator's sole discretion. The services must be: • 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 sickness, injury, mental illness, substance use disorder disease or its symptoms; • not mainly for your convenience or that of your doctor or other health care provider; and • not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms. *Generally Accepted Standards of Medical Practice* are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that

If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. The Claims Administrator reserves the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be within the Claims Administrator's sole discretion. The Claims Administrator develops and maintains clinical policies that describe the Generally Accepted Standards of Medical Practice scientific evidence, prevailing medical standards and clinical guidelines supporting its determinations regarding specific services. These clinical policies as developed by the Claims Administrator are revised from time to time. Aetna publishes information concerning utilization review and our medical necessity criteria here: **https://www.aetna.com/health-care-professionals/utilization-management.html** Within that site, there is a section dedicated specially to the criteria used for behavioral health conditions, which can be found here: **https://www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html**. We also publish clinical policy bulletins concerning services we may or may not cover, including behavioral health services that may be excluded on grounds that they are experimental and investigational, which detail the evidentiary bases for our coverage or exclusion determinations: **https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html** **Covered services:** All inpatient, outpatient and emergency care services **Plan language:**	suggest a causal relationship between the service or treatment and health outcomes. If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. The Claims Administrator reserves the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be within the Claims Administrator's sole discretion. The Claims Administrator develops and maintains clinical policies that describe the Generally Accepted Standards of Medical Practice scientific evidence, prevailing medical standards and clinical guidelines supporting its determinations regarding specific services. These clinical policies as developed by the Claims Administrator are revised from time to time. Aetna publishes information concerning utilization review and our medical necessity criteria here: **https://www.aetna.com/health-care-professionals/utilization-management.html** Within that site, there is a section dedicated specially to the criteria used for behavioral health conditions, which can be found here: **https://www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html**. We also publish clinical policy bulletins concerning services we may or may not cover, including behavioral health services that may be excluded on grounds that they are experimental and investigational, which detail the evidentiary bases for our coverage or exclusion determinations: **https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html** **Covered services:** All inpatient, outpatient and emergency care services

➢ Section # MD 2021 / Form # **AL SG HCOC-2021-EPO 05**/ Page # 13, 99-100 ## Medical necessity and precertification requirements The starting point for **covered benefits** under your plan is whether the services and supplies are **eligible health services**. See the *Eligible health services under your plan* and *Exceptions* sections plus the schedule of benefits. Your plan pays for its share of the expense for **eligible health services** only if the general requirements are met. They are: • The **eligible health service** is **medically necessary**. • You get the **eligible health service** from a **network provider**. • You or your **provider precertifies** the **eligible health service** when required. This section addresses the **medical necessity** and **precertification** requirements. You will find the advantages of using a **network provider** and any exceptions in the *Who provides the care* section. ## Medically necessary; medical necessity As we said in the *Let's get started!* section, **medical necessity** is a requirement for you to receive **eligible health services** under this plan. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**". That's where we also explain what our medical directors, or a **physician** they assign, consider when determining if an **eligible health service** is **medically necessary**.	**Plan language:** ➢ Section # MD 2021 / Form # **AL SG HCOC-2021-EPO 05**/ Page # 13, 99-100 ## Medical necessity and precertification requirements The starting point for **covered benefits** under your plan is whether the services and supplies are **eligible health services**. See the *Eligible health services under your plan* and *Exceptions* sections plus the schedule of benefits. Your plan pays for its share of the expense for **eligible health services** only if the general requirements are met. They are: • The **eligible health service** is **medically necessary**. • You get the **eligible health service** from a **network provider**. • You or your **provider precertifies** the **eligible health service** when required. This section addresses the **medical necessity** and **precertification** requirements. You will find the advantages of using a **network provider** and any exceptions in the *Who provides the care* section. ## Medically necessary; medical necessity As we said in the *Let's get started!* section, **medical necessity** is a requirement for you to receive **eligible health services** under this plan. The **medical necessity** requirements are in the *Glossary* section, where we define "**medically necessary, medical necessity**". That's where we also explain what our medical directors, or a **physician** they assign, consider when determining if an **eligible health service** is

Medically necessary, medical necessity Health care services that we determine a **provider** using sensible 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 the same benefit 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 based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community • Consistent with the standards set forth in policy issues involving clinical judgment	**medically necessary**. **Medically necessary, medical necessity** Health care services that we determine a **provider** using sensible 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 the same benefit 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 based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community • Consistent with the standards set forth in policy issues involving clinical judgment

B. Identify the factors used in the development of the limitation(s);

Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

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:

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

No formula is used for weighting these factors. CPC members apply their clinical training and expertise in evaluating them.

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

- Factor: The technology must have final approval from the appropriate governmental regulatory bodies
- Source: Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies

All other factors share these sources:

- 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

D. Identify the methods and analysis used in the development of the limitation(s); and

Aetna's strategy regarding satisfaction of parity's NQTL requirements includes the utilization of an identical standard/definition of medical necessity.

Medical and BH utilize appropriately applicable and generally accepted standards of practice to guide clinicians with coverage determinations.

Every individual MH/SUD medical necessity determination is afforded independent clinical consideration based on the member's presentation. This point is made clear to Aetna clinicians making medical necessity determinations in both the medical necessity tools utilized and in staff training. Consistent with National Clinical Services (NCS) 503 Medical Review Policy & Procedure (attached), staff considers the individual needs of the member when applying criteria or guidelines, including, but not limited to:

- Age;
- Co-morbidities;
- Complications;
- Progress of treatment;
- Need for skilled care;
- Psychosocial situation;
- Risk related to ethnicity or genetic factors;
- Home environment, when applicable.

The medical necessity criteria are used in distinct circumstances; there is no priority in how they are applied. For inpatient medical stays, Aetna utilizes Milliman Care Guidelines (MCG) as a guideline to determine the medical necessity. For substance use disorder treatments, Aetna utilizes criteria developed by the American Society of Addiction Medicine (or ASAM) as a guideline to determine medical necessity For mental health treatments, Aetna utilizes the Level of Care Utilization System (LOCUS) and the Child and Adolescent Level of Care Utilization System/Child and Adolescent Service Intensity Instrument (CALOCUS/CASII) for its medical necessity reviews. More information about LOCUS, CALOCUS/CASSII and ASAM criteria can be found on Aetna's website at https://www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html. These criteria (MCG, ASAM, LOCUS, and CALOCUS/CASSII) are used to determine the level of care, or the setting in which care is provided. Clinical Policy Bulletins (CPBs) are guidelines for determining the medical necessity of procedures, services and drugs; not the setting in which those are provided.

- Inpatient:
  - M/S: MCG and CPBs
  - MH/SUD: LOCUS, CALOCUS, ASAM and CPBs
- Outpatient (Office and All Other):
  - M/S: CPBs
  - MH/SUD: LOCUS, CALOCUS, ASAM and CPBs
- Emergency:
  - M/S: CPBs
  - MH/SUD: CPBs

All Aetna clinicians are educated and informed of MHPAEA's requirements. The enterprise mandates each year every colleague to complete the compliance training for mental health parity. The course explains mental health parity, how it impacts members and the role the enterprise employees have in supporting it.

The definition of medical necessity for both MH/SUD and medical/surgical share the same definition in our standard Certificates of coverage. Additionally, the Clinical Policy Bulletins (CPB) and evidence-based guidelines used in the medical necessity review process have been found to be aligned to generally accepted practice standards. This validation is completed by our Clinical Policy Council and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines. Upon request, Aetna's Clinical Policy Research and Development Team evaluates and renders an opinion on the experimental and investigational status and medical necessity of medical services or a technology that is considered for coverage under Aetna medical benefit plans.

Requests usually come from Aetna's clinical staff (medical or pharmacy directors or other clinical staff) in the context of preauthorization, precertification, or retrospective claim review. In some instances, an assessment may be conducted at the request of other business areas of Aetna (e.g., Aetna's Special Investigations Unit, Legal Department, Aetna Senior Management), from Aetna's National Quality Advisory Committees (NQAC), from medical technology vendors (e.g. pharmaceutical or medical device manufacturers), or from participating Aetna healthcare providers. In addition, the Clinical Policy Research and Development Team may initiate an assessment at its own initiative, based on new information about a medical technology that is material to its experimental and investigational status and medical necessity.

The Senior Director, Clinical Policy Research & Development and the Chairman of the Clinical Policy Council determine whether a new or revised Clinical Policy Bulletin (CPB) on the medical technology needs to be drafted. The following factors are considered in prioritizing requests for revising or creating new CPBs:

1. Whether a new policy or policy revision is necessary to support specific Aetna clinical functions (e.g., precertification, claim reimbursement, special investigations, etc.);
2. The potential impact of the medical technology on Aetna and its members;
3. The quantity and importance of questions that have arisen regarding the medical technology;
4. New evidence, guidelines, consensus statements or other information that is material to the experimental and investigational status and medical necessity of the medical technology;
5. Changes in the regulatory status of the medical technology relevant to its experimental and investigational status and medical necessity.

Clinical Policy Bulletins are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other relevant new information warrants more frequent review. The CPB development process includes annual assessment of new and emerging evidence-based information, including clinical information related to health equity, such as that related to race, ethnicity, gender, and underserved populations. Each time a CPB is updated, a comprehensive search of the peer-reviewed, published medical literature is performed to determine if there is a change in the experimental and investigational status or medical necessity of the medical technologies addressed. If the Clinical Policy Research and Development Team determines that new evidence or other information has emerged to warrant a change in Aetna's clinical policy, a revised

CPB draft is prepared. If no new evidence has emerged that would warrant a change in Aetna's position, the CPB may be updated with additional supporting background information and references. Each revised CPB is submitted to Aetna's Clinical Policy Council for review and approval. Additional changes to the revised or updated draft CPB may be made upon the recommendations of the Clinical Policy Council.

Approved new, revised, and updated CPBs become effective when they are published on Aetna's CPB websites. A complete index of published CPBs can be found on Aetna's external CPB website. The publication history of each CPB can be found in the Policy History section of the CPB. A summary of recently published new, revised, and updated CPBs is published on Aetna's external CPB What's New website.

The medical necessity criteria, as defined, are applied equally as written. The same definition applies to M/S and MH/SUD services. We do not have different versions of the criteria definitions that apply specifically to M/S versus MH/SUD services.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

Aetna's medical necessity coverage policy development and application process is consistent between mental health/substance use disorder (MH-SUD) and medical/surgical (M/S). Aetna applies comparable evidence-based guidelines to define established standards of effective care in both M/S and MH/SUD benefits. Consistency in policy development, process and application evidences compliance with the NQTL requirement that the definition of medical necessity be applied comparably, and no more stringently, to MH/SUD services than to M/S services.

An "in operation" review of Aetna's application of the medical necessity NQTL, specifically Aetna's clinical policies, medical review journals or peer reviewed research, or the decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion revealed no statistically significant discrepancies in medical necessity denial rates as-between MH/SUD and M/S benefits. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement.

A review of the in-operation medical necessity review data shows fewer medical necessity denials for MH/SUD than for M/S overall. A review of claim denials shows the MH/SUD claims identified as denials were not denied as not medically necessary, with the exception of the few that were addressed.

Consequently, Aetna concludes that the medical necessity NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

2. **Prior Authorization Review Process**

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits	MH/SUD Benefits
Precertification/Prior Authorization Precertification does not apply to any medical surgical or MH/SUD benefits in the Outpatient-Office Visit (In-network and Out of Network) Classification. Precertification only applies to the medical/surgical benefit of Fixed-wing Aircraft Transport in the Emergency Classification. Precertification is required for all inpatient admissions for both MH/SUD and medical/surgical services. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) The only factor is whether the services or items are in the inpatient classification. Because precertification is required for all inpatient admissions for both MH/SUD and medical/surgical services, the NQTL is identical as between medical/surgical and MH/SUD services, and a comparability analysis of the in-writing component of factors and evidentiary standards is not required. The Department of Labor's Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act states on page 23: "If only certain benefits are subject to an NQTL, such as meeting a fail-first protocol or requiring preauthorization, plans and issuers should have information available to substantiate how the applicable factors were used to apply the specific NQTL to medical/surgical and MH/SUD benefits." Precertification applies to four MH/SUD Outpatient All Other benefits: Applied Behavior Analysis, Partial Hospitalization, Transcranial Magnetic Stimulation and Gender Affirming Surgery. Precertification applies to numerous medical/surgical Outpatient All Other benefits (for example, Outpatient surgery, Private Duty Nursing,	**Precertification/Prior Authorization** Precertification does not apply to any medical surgical or MH/SUD benefits in the Outpatient-Office Visit (In-network and Out of Network) Classification. Precertification only applies to the medical/surgical benefit of Fixed-wing Aircraft Transport in the Emergency Classification. Precertification is required for all inpatient admissions for both MH/SUD and medical/surgical services. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) The only factor is whether the services or items are in the inpatient classification. Because precertification is required for all inpatient admissions for both MH/SUD and medical/surgical services., the NQTL is identical as between medical/surgical and MH/SUD services, and a comparability analysis of the in-writing component of factors and evidentiary standards is not required. The Department of Labor's Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act states on page 23: "If only certain benefits are subject to an NQTL, such as meeting a fail-first protocol or requiring preauthorization, plans and issuers should have information available to substantiate how the applicable factors were used to apply the specific NQTL to medical/surgical and MH/SUD benefits." Precertification applies to four MH/SUD Outpatient All Other benefits: Applied Behavior Analysis, Partial Hospitalization, Transcranial Magnetic Stimulation and Gender Affirming Surgery. Precertification applies to numerous medical/surgical Outpatient All Other benefits (for example, Outpatient surgery, Private Duty Nursing,

Proton beam Radiotherapy, and Electric or Motorized Wheelchairs and Scooters). Please refer to most up-to date Participating Provider Precertification List for Medical/Surgical services and the Behavioral Health Precertification List for MH/SUD services, which is subject to change from time to time. See https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For Medical/Surgical: All outpatient all other non-palliative procedures, services, devices, and therapies on the National Precertification List (NPL) **https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html** **Plan language:** ➢ Section # MD 2021 / Form # AL SG HCOC-2021-EPO 05/ Page # 13, 49-50, 102, 105 **Precertification** You need pre-approval from us for some **eligible health services**. Pre-approval is also called **precertification**. **In-network**: Your **physician** or **PCP** is responsible for obtaining any necessary **precertification** before you get the care. For	Proton beam Radiotherapy, and Electric or Motorized Wheelchairs and Scooters). Please refer to most up-to date Participating Provider Precertification List for Medical/Surgical services and the Behavioral Health Precertification List for MH/SUD services, which is subject to change from time to time. See https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) **https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf** **Plan language:** ➢ Section # MD 2021 / Form # AL SG HCOC-2021-EPO 05/ Page # 13, 49-50, 102, 105 **Precertification** You need pre-approval from us for some **eligible health services**. Pre-approval is also called **precertification**.

precertification of outpatient **prescription drugs**, see *Eligible health services under your plan – Outpatient prescription drugs – What precertification requirements apply*. If your **physician** or **PCP** doesn't get a required **precertification**, we won't pay the **provider** who gives you the care. You won't have to pay either if your **physician** or **PCP** fails to ask us for **precertification**. If your **physician** or **PCP** requests **precertification** and we refuse it, you can still get the care but the plan won't pay for it. You will find details on requirements in the *What the plan pays and what you pay - Important note – when you pay all* section. 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. ## What precertification requirements apply **Why do some drugs need precertification?** For certain drugs, you, your **prescriber** or your pharmacist needs to get approval from us before we will cover the drug. This is called "**precertification**". The requirement for getting approval in advance guides appropriate use of precertified drugs and makes sure they are **medically necessary**. **Precertification** will not be required more than once per year or for the duration of treatment of the chronic	**In-network**: Your **physician** or **PCP** is responsible for obtaining any necessary **precertification** before you get the care. For **precertification** of outpatient **prescription drugs**, see *Eligible health services under your plan – Outpatient prescription drugs – What precertification requirements apply*. If your **physician** or **PCP** doesn't get a required **precertification**, we won't pay the **provider** who gives you the care. You won't have to pay either if your **physician** or **PCP** fails to ask us for **precertification**. If your **physician** or **PCP** requests **precertification** and we refuse it, you can still get the care but the plan won't pay for it. You will find details on requirements in the *What the plan pays and what you pay - Important note – when you pay all* section. 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. ## What precertification requirements apply **Why do some drugs need precertification?** For certain drugs, you, your **prescriber** or your pharmacist needs to get approval from us before we will cover the drug. This is called "**precertification**". The requirement for getting approval in advance guides appropriate use of precertified drugs and makes sure they are **medically necessary**. **Precertification** will not be required more than

condition, whichever is less. For the most up-to-date information, call us or go online. See the *How to contact us for help* section for details. **Precertification, precertify** A requirement that you or your **physician** contact us before you receive coverage for certain services. This may include a determination by us as to whether the service is **medically necessary** and eligible for coverage.	once per year or for the duration of treatment of the chronic condition, whichever is less. For the most up-to-date information, call us or go online. See the *How to contact us for help* section for details. **Precertification, precertify** A requirement that you or your **physician** contact us before you receive coverage for certain services. This may include a determination by us as to whether the service is **medically necessary** and eligible for coverage.

B. Identify the factors used in the development of the limitation(s);

Factors for Adding a Service to the NPL: *Note: All factors are the same for medical/surgical and MH/SUD. All services must meet one or more of the below three criteria to be added to the NPL.*

- Cost: Cost of treatment is satisfied when the average paid Medicare rate is at least $150 for the service being considered (based on Aetna's national paid Medicare claims experience)
- High-cost growth (projected or actual): Whether, based on internal Aetna claims data, the per member per month expense for the services increased more than 10% in the most recent two-year period compared to an initial year baseline. (For example, if the 2015 per member per month (PMPM)=$1.00, the 2016 PMPM=$2.00, and the 2017 PMPM=$3.00, then that would be a 200% trend increase over the two-year period - calculate by subtracting the 2015 PEPM from the 2017 PMPM and then dividing by the 2015 PMPM.)
- Variability in cost and practice: Internal claims data demonstrates that there is greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period, raising quality of care concerns.

Extenuating Factors for adding a service to the NQTL (precertification). The NPL Committee may add a service that does not meet the above criteria, based on the following Extenuating Factors:

- Patient safety: Considers whether precertification can minimize potential harm to a member, particularly for life changing procedures that are irreversible post-surgery.
- Clinical quality control: Refers to ensuring a provider and proposed treatment are qualified and appropriate so that the possibility of adverse outcomes is reduced.

- Marked variation in provider utilization patterns: Refers to there being a significant range providers' utilization of the service, drug or device, suggesting that some of the utilization may be unnecessary.
- Incorrect utilization: Refers to the potential that a given service, drug or device is not appropriate for the member's condition.
- Application of Clinical Policy Bulletin (CPB) requirements: Refers to the opportunity to make determinations required under Aetna's CPBs and other clinical policies pertaining to the experimental/investigational nature of a service, appropriate use of new/changing technology, step therapy, or site of service.
- Standards of industry practice: Refers to what other health insurers and administrators have decided to be appropriate in terms of precertification.

There are no fixed quantitative standards for the above factors; rather they are evaluated in comparison to other services in the same benefit classification.

Factors for retaining a Service to the NPL:

- ROI 3:1 or greater - retain
- ROI 2 to 2.9:1
- ROI </= 1.9:1 and NOT integral to NPL Group/Category (example, breast reduction code may independently have a low ROI, but it is part of a procedure group for which precertification is required) - consider Extenuating Factors

* While ROI may be the primary factor used to determine retention of a service on the NPL, it is not an absolute determinant. The NPL Committee may consider the factors for adding a service to the NPL and/or any Extenuating Factors. There are no fixed quantitative standards for the factors; rather they are evaluated in comparison to other services in the same benefit classification.

No other factors were considered and rejected. No factors were weighted more than another.

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

Sources:

- For Cost: Review of Medicare rates
- For Cost, High-cost growth, and Variability in cost and practice: Internal claims data
- For ROI: Internal admin cost data
- For Extenuating Factors: Clinical resources, clinical training, expertise and judgment
- For Extenuating Factors: Clinical Policy Bulletins
- For Extenuating Factors: Standards of industry practice

No other sources were considered and rejected. No sources were weighted more than another.

Evidentiary Standards:

- 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.)

D. Identify the methods and analysis used in the development of the limitation(s); and

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. 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.

NPL voting members are Medical Directors, including Behavioral Health Medical Directors; all voting members have comparable clinical expertise. Business partners are clinicians and other subject matter experts who represent a broad range of Aetna programs. The voting members collaborate and solicit input from key business partners to assure delivery of a consistent guideline of high quality.

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 RNs, licensed clinical social workers 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 the 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.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

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.

Operational proportionality data show a lower percentage of MH/SUD services than M/S subject to precertification reviews to total claims in the INN OP-All Other classification. This demonstrates that the NQTL is not more stringently applied to MH/SUD services than M/S services.

Overturn rates for appeals: Precertification review data, from the UR database, for 2021 show zero MH/SUD appeals of precertification decisions. Therefore, there were no peer-to-peer reviews. With no MH/SUD appeals to analyze, it is apparent that the NQTL is not more stringently applied to MH/SUD services than M/S services.

The Internal Quality Reviews and Inter-Rater Reliability process provides a way to evaluate whether precertification and concurrent review of MH/SUD and M/S services is performed comparably, and not more stringently for MH/SUD, in operation. These reports show that both Medical and Behavioral Health Medical Directors and clinicians are performing precertification and concurrent review accurately and consistently.

An “in operation” review of Aetna’s application of the precertification NQTL, specifically Denial Rates for INN, OON MH/SUD, M/S retrospective reviews, and overturn rates for appeals show no statistically significant discrepancies between MH/SUD and M/S reviews. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement.

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 5 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 2021 annual retention review, no MH/SUD or M/S services that met the ROI were removed from the NPL. All MH/SUD services met the ROI and were retained on the NPL. 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.

3. **<u>Concurrent Review Process</u>**

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits	MH/SUD Benefits
Concurrent review is performed by licensed healthcare professionals to review the medical necessity of a patient's care while in the hospital or while undergoing outpatient treatment, 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 and outpatient services subject to precertification that entails an ongoing course of treatment. Concurrent Review does not apply to any medical surgical benefit in the Outpatient – Office Visit (INN and OON) Classification. All medical/surgical inpatient admissions are subject to concurrent review. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) The only factor is whether the services or items are in the inpatient classification. Concurrent review applies to numerous medical/surgical Outpatient All Other benefits (for example, Outpatient surgery, Private Duty Nursing, Proton beam Radiotherapy, and Electric or Motorized Wheelchairs and Scooters). Please refer to most up-to date Participating Provider Precertification List for Medical/Surgical	Concurrent review is performed by licensed healthcare professionals to review the medical necessity of a patient's care while in the hospital or while undergoing outpatient treatment, 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 and outpatient services subject to precertification that entails an ongoing course of treatment. Concurrent Review does not apply to any MH/SUD benefit in the Outpatient – Office Visit (INN and OON) Classification. All MH/SUD inpatient admissions are subject to concurrent review. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) The only factor is whether the services or items are in the inpatient classification. Concurrent review applies to four MH/SUD Outpatient All Other benefits: Applied Behavior Analysis, Partial Hospitalization, Transcranial Magnetic Stimulation and Gender Affirming Surgery. Please refer to most up-to date Behavioral Health Precertification List for MH/SUD services, which is subject to change from time to time. See

services, which is subject to change from time to time. See https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/2023_Precert_List.pdf All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For Medical/Surgical: All outpatient all other non-palliative procedures, services, devices, and therapies on the National Precertification List (NPL) https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/2023_Precert_List.pdf **Plan language:** ➢ Section # MD 2021 / Form # **AL SG HCOC-2021-EPO 05**/ Page # 70 Concurrent Care Claim Extension: Following a request for a Concurrent Care Claim Extension, **Aetna** will make notification of a claim determination for emergency or urgent care as soon as possible but not later than 24 hours, with respect to emergency or urgent care provided the request is received at least 24 hours prior to the expiration of the approved course of treatment,	https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf **Plan language:** ➢ Section # MD 2021 / Form # **AL SG HCOC-2021-EPO 05**/ Page # 70 Concurrent Care Claim Extension: Following a request for a Concurrent Care Claim Extension, **Aetna** will make notification of a claim determination for emergency or urgent care as soon as possible but not later than 24 hours, with respect to emergency or urgent care provided the request is received at least 24 hours prior to the expiration of the approved course of treatment, and 1 working day with respect to all other care, following a request for a Concurrent Care Claim Extension.

and 1 working day with respect to all other care, following a request for a Concurrent Care Claim Extension. Concurrent Care Claim Reduction or Termination: **Aetna** will make notification of a claim determination to reduce or terminate a previously approved course of treatment with enough time for the covered person to file an appeal. **Aetna** will not deny reimbursement to a health care provider for the pre-authorized or approved service delivered to the covered person unless; the information submitted to **Aetna** regarding the service to be delivered to the covered person was fraudulent or intentionally misrepresentative; critical information requested by **Aetna** regarding the service to be delivered to the covered person was omitted such that **Aetna's** determination would have been different had it known the critical information; a planned course of treatment for the covered person that was approved by **Aetna** was not substantially followed by the health care provider; or on the date the pre-authorized or approved service was delivered: the covered person was not covered by **Aetna**; **Aetna** maintained an automated eligibility verification system that was available to the contracting provider by telephone or via the Internet; and according to the verification system, the covered person was not covered by **Aetna**.	Concurrent Care Claim Reduction or Termination: **Aetna** will make notification of a claim determination to reduce or terminate a previously approved course of treatment with enough time for the covered person to file an appeal. **Aetna** will not deny reimbursement to a health care provider for the pre-authorized or approved service delivered to the covered person unless; the information submitted to **Aetna** regarding the service to be delivered to the covered person was fraudulent or intentionally misrepresentative; critical information requested by **Aetna** regarding the service to be delivered to the covered person was omitted such that **Aetna's** determination would have been different had it known the critical information; a planned course of treatment for the covered person that was approved by **Aetna** was not substantially followed by the health care provider; or on the date the pre-authorized or approved service was delivered: the covered person was not covered by **Aetna**; **Aetna** maintained an automated eligibility verification system that was available to the contracting provider by telephone or via the Internet; and according to the verification system, the covered person was not covered by **Aetna**.

B. Identify the factors used in the development of the limitation(s);

Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

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.

Factors used in determining how concurrent review is performed:

- National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization Accreditation
- Applicable state and federal law

No other factors were considered and rejected. No factors were weighted more than another.

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

Sources:

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).

D. Identify the methods and analysis used in the development of the limitation(s); and

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.

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. 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.

NPL voting members are Medical Directors, including Behavioral Health Medical Directors; all voting members have comparable clinical expertise. Business partners are clinicians and other subject matter experts who represent a broad range of Aetna programs. The voting members collaborate and solicit input from key business partners to assure delivery of a consistent guideline of high quality.

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 clinical social workers or physicians. 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.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

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.

Aetna's concurrent review policy development and application process is consistent between MH/SUD and M/S. Aetna applies comparable evidence-based guidelines to define established standards of effective care in both M/S and MH/SUD benefits. Consistency in policy development, process and application evidences compliance with the NQTL requirement that the concurrent review process be applied comparably, and no more stringently, to MH/SUD services than to M/S services.

Aetna's Inter-Rater Reliability and Internal Quality Review processes provide a way to evaluate whether precertification and concurrent 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. These reports show that both Medical and Behavioral Health Medical Directors and clinicians are performing precertification and concurrent review accurately and consistently.

An “in operation” review of Aetna’s application of the concurrent review process NQTL, specifically denial rates and turnaround times for INN and OON concurrent reviews, overturn rates for appeals, and Internal Quality Review and Inter-Rater Reliability assessments revealed no statistically significant discrepancies in concurrent review denial rates as-between MH/SUD and M/S benefits. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement.
Consequently, Aetna concludes that the concurrent review process NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

4. **Retrospective Review Process**

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits	MH/SUD Benefits
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 determine benefits and eligibility. For OON services, Aetna performs retrospective review on OON Inpatient services that were not pre-certified 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 "emergency" M/S and MH/SUD services where the diagnosis code signifies a non-emergent condition. **M/S 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	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 determine benefits and eligibility. For OON services, Aetna performs retrospective review on OON Inpatient services that were not pre-certified 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 "emergency" M/S and MH/SUD services where the diagnosis code signifies a non-emergent condition. **MH/SUD services NQTL applies to:** 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" M/S services on the NonEmergent ER Diagnosis List **Plan language:** Refer to the plan language for precertification. **https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/2023_Precert_List.pdf** Plan language: AL SG HCOC-2021-EPO 05 / Page #24 ## Emergency services and urgent care **Eligible health services** include services and supplies for the treatment of an **emergency medical condition** or an **urgent condition**. As always, you can get **emergency services** from **network providers**. However, you can also get **emergency services** from **out-of-network providers.** Your coverage for **emergency services** and urgent care from **out-of-network providers** ends when the attending **physician** and we determine that you are medically able to travel or to be transported to a **network provider** if you need more care. Follow-up care must be provided by your **physician**, **PCP** or **specialist**. See the *Medical necessity and precertification requirements* section for more information.. ## In case of a medical emergency When you experience an **emergency medical condition**, you should go to the nearest emergency room. You can also dial 911 or your local emergency response service for medical and **ambulance** assistance. If possible, call your **physician**, but only if a delay will not harm your health.	"Emergency" M/S services on the NonEmergent ER Diagnosis List **Plan Language:** Refer to the plan language for precertification. **https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf** Plan language: AL SG HCOC-2021-EPO 05 / Page #24 ## Emergency services and urgent care **Eligible health services** include services and supplies for the treatment of an **emergency medical condition** or an **urgent condition**. As always, you can get **emergency services** from **network providers**. However, you can also get **emergency services** from **out-of-network providers.** Your coverage for **emergency services** and urgent care from **out-of-network providers** ends when the attending **physician** and we determine that you are medically able to travel or to be transported to a **network provider** if you need more care. Follow-up care must be provided by your **physician**, **PCP** or **specialist**. See the *Medical necessity and precertification requirements* section for more information.. ## In case of a medical emergency When you experience an **emergency medical condition**, you should go to the nearest emergency room. You can also dial 911 or your local emergency response service for medical and **ambulance** assistance. If possible, call your **physician**, but only if a delay will not harm your health.

Non-emergency condition If you go to an emergency room for what is not an **emergency medical condition**, the plan may not cover your expenses. See the schedule of benefits and the *Exceptions* and *Glossary* sections for specific information. **Page 97** **Emergency medical condition** A medical condition with symptoms that are acute or severe enough to lead a prudent layperson to reasonably believe that failure to get immediate medical care for the condition, **illness**, or **injury** could result in any of the following: • Placing their health in serious danger • Serious impairment to bodily function • Serious loss of function to a body part or organ • Serious danger to the health of their unborn child **Emergency services** Treatment given in a **hospital**'s emergency room or freestanding medical facility for an **emergency medical condition**. This includes: a medical screening examination; ancillary services necessary to evaluate the condition and such further medical examinations, evaluations and treatment required to stabilize, an **emergency medical condition**.	**Non-emergency condition** If you go to an emergency room for what is not an **emergency medical condition**, the plan may not cover your expenses. See the schedule of benefits and the *Exceptions* and *Glossary* sections for specific information. **Page 97** **Emergency medical condition** A medical condition with symptoms that are acute or severe enough to lead a prudent layperson to reasonably believe that failure to get immediate medical care for the condition, **illness**, or **injury** could result in any of the following: • Placing their health in serious danger • Serious impairment to bodily function • Serious loss of function to a body part or organ • Serious danger to the health of their unborn child **Emergency services** Treatment given in a **hospital**'s emergency room or freestanding medical facility for an **emergency medical condition**. This includes: a medical screening examination; ancillary services necessary to evaluate the condition and such further medical examinations, evaluations and treatment required to stabilize, an **emergency medical condition**.

B. Identify the factors used in the development of the limitation(s);

Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

The factors used in determining what services are subject to precertification and, by extension, to retrospective review, are described in Aetna's Prior Authorization NQTL Comparative Analysis.

Additional factors used in determining which services are subject to retrospective review are:

- Terms of Aetna's contracts with INN providers
- State and federal laws pertaining to waiver of INN provider precertification requirements
- Federal Law defining "prudent layperson" standard for emergency services
- ICD10 and DSM-V Coding Descriptions

The factors used in determining how retrospective review is performed 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

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

Sources:
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. The Medical Directors on the PPDC reviewICD10 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.

Federal law defining "prudent layperson" standard for emergency services:
An emergency medical condition is:

- Manifesting itself by acute symptoms of severity (including severe pain) such that a prudent layperson who has an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in:
- Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman and her unborn child) in serious jeopardy
- Serious impairment to bodily functions, or
- Serious dysfunction of any bodily organ or part.

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.

D. Identify the methods and analysis used in the development of the limitation(s); and

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. 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 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 1495 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.

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 clinical social workers or physicians. 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.) 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.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

Aetna's retrospective review policy development and application process is consistent between MH-SUD and M/S. Aetna applies comparable evidence-based guidelines to define established standards of effective care in both M/S and MH/SUD benefits. Consistency in policy development, process and application evidence compliance with the NQTL requirement that the retrospective review process be applied comparably, and no more stringently, to MH/SUD services than to M/S services.

Operational proportionality data show a lower percentage of MH/SUD services than M/S subject to retrospective reviews to total claims in the INN OP-All Other classification. This demonstrates that the NQTL is not more stringently applied to MH/SUD services than M/S services.

Overturn rates for appeals: Retrospective review data, from the UR database, for 2021 show zero MH/SUD appeals of retrospective review decisions. Therefore, there were no peer-to-peer reviews. With no MH/SUD appeals to analyze, it is apparent that the NQTL is not more stringently applied to MH/SUD services than M/S services.

The Internal Quality Reviews and Inter-Rater Reliability process provides a way to evaluate whether precertification and concurrent review of MH/SUD and M/S services is performed comparably, and not more stringently for MH/SUD, in operation. These reports show that both Medical and Behavioral Health Medical Directors and clinicians are performing precertification and concurrent review accurately and consistently.

An "in operation" review of Aetna's application of the retrospective review NQTL, specifically Denial Rates for INN, OON MH/SUD, M/S retrospective reviews, and overturn rates for appeals for all but one plan, there were no denials of retrospective reviews. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement.

Consequently, Aetna concludes that the retrospective review NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

5. Emergency Services

NQTLs applicable to emergency services are described in other sections: 1. Medical Necessity; 4. Retrospective Review; 10. Provider Credentialing and Contracting; 14. Reimbursement for Providers and Facilities.

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

B. Identify the factors used in the development of the limitation(s);

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

D. Identify the methods and analysis used in the development of the limitation(s); and

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

6. <u>Pharmacy Services</u>

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits in Prescription Classification	MH/SUD Benefits in Prescription Classification
<u>Pharmacy Prior Authorization:</u> Pharmacy prior authorization is typically utilized in drug classes where the potential for use for unapproved indications exists, the potential for inappropriate over- or under-utilization exists, or when safety concerns exist with a drug or drug class. Cost may also be a consideration in determining if prior authorization is appropriate. HI SG HOC-2021 05 pg 50 **What precertification requirements apply** **Why do some drugs need precertification?** For certain drugs, you, your **prescriber** or your pharmacist needs to get approval from us before we will cover the drug. This is called "**precertification**". The requirement for getting approval in advance guides appropriate use of **precertified** drugs and makes sure they are **medically necessary**. **Precertification** will not be required more than once per year or for the duration of treatment of the chronic condition, whichever is less. For the most up-to-date information, call us or go online. See the *How to contact us for help* section for details. You will not need to obtain a new certification for a **prescription drug** if: • You change **Aetna** plans and the **prescription drug** is also covered under the new plan • The dosage on the approved drug changes and the	**Pharmacy Prior Authorization:** Pharmacy prior authorization is utilized in drug classes where the potential for use for unapproved indications exists, the potential for inappropriate over- or under-utilization exists, or when safety concerns exist with a drug or drug class. Cost may also be a consideration in determining if prior authorization is appropriate. HI SG HOC-2021 05 pg 50 **What precertification requirements apply** **Why do some drugs need precertification?** For certain drugs, you, your **prescriber** or your pharmacist needs to get approval from us before we will cover the drug. This is called "**precertification**". The requirement for getting approval in advance guides appropriate use of **precertified** drugs and makes sure they are **medically necessary**. **Precertification** will not be required more than once per year or for the duration of treatment of the chronic condition, whichever is less. For the most up-to-date information, call us or go online. See the *How to contact us for help* section for details. You will not need to obtain a new certification for a **prescription drug** if: • You change **Aetna** plans and the **prescription drug** is also covered under the new plan • The dosage on the approved drug changes and the

changes are consistent with the Food and Drug Administration labeled dosages	changes are consistent with the Food and Drug Administration labeled dosages
The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions.	The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions.
The decision to develop prior authorization is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the duration or quantity of therapy needed by most patients, as well as evidence-based reviews of the medical literature and relevant clinical information. UM tools, including PA, should not cause delay of care or have an impact on, impede or prevent emergency or urgent access to medication. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.	The decision to develop prior authorization is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the duration or quantity of therapy needed by most patients, as well as evidence-based reviews of the medical literature and relevant clinical information. UM tools, including PA, should not cause delay of care or have an impact on, impede or prevent emergency or urgent access to medication. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.
Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug, and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM Criteria developed for medications used in mental health conditions require the same levels of clinical	Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug, and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM Criteria developed for medications used in mental health conditions require the same levels of clinical

evidence as those that are not used or indicated for mental health conditions. **MED/SURG drugs with Prior Auth:** **(Below are examples of MED/SURG drugs with Prior Auth)** **EXCHANGE FORMULARY** Sovaldi Harvoni Lenvima Xtandi Sprycel Forteo Prolia Humatrope Omnitrope Creon Zenpep Wakix Aubagio Gilenya Xtampza ER Nucynta Enbrel Humira Taltz Skyrizi **Pharmacy Step Therapy (ST):** Step therapy is a pharmacy UM strategy typically employed in therapeutic classes with broad generic availability. Step Therapy is generally used to promote the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent, with the potential for reduced cost from greater utilization of generics and/or lower cost brands. HI SG HOC-2021 05 pg 50-51	evidence as those that are not used or indicated for mental health conditions. **MH/SUD drugs with Prior Auth:** **EXCHANGE FORMULARY** Emsam Latuda Nuplazid caps, tabs Belsomra Hetlioz caps, oral susp Acamprosate DR **Pharmacy Step Therapy:** Step therapy is a pharmacy UM strategy employed in therapeutic classes with broad generic availability. Step Therapy is used to promote the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent, with the potential for reduced cost from greater utilization of generics and/or lower cost brands. HI SG HOC-2021 05 pg 50-51 There is another type of **precertification** for **prescription drugs**, and that is **step therapy**. You will find the **step therapy prescription drugs** on the **drug guide**. For the most up-to-date information, call us or go online. See the How to contact us for help section for details. We will waive **step therapy** if the **step therapy prescription drug** has not been approved by the U.S. Food and Drug Administration (FDA) for the medical condition being treated, or if your **prescriber** provides supporting medical information showing that: • The drug was ordered for you within the past 180 days;

There is another type of **precertification** for **prescription drugs**, and that is **step therapy**. You will find the **step therapy prescription drugs** on the **drug guide**. For the most up-to-date information, call us or go online. See the How to contact us for help section for details.

We will waive **step therapy** if the **step therapy prescription drug** has not been approved by the U.S. Food and Drug Administration (FDA) for the medical condition being treated, or if your **prescriber** provides supporting medical information showing that:

- The drug was ordered for you within the past 180 days; and
- In your prescriber's opinion, it is effective in treating your disease or condition

In addition, we will waive **step therapy** or fail-first protocol if the **step therapy prescription drug** is used to treat stage four advance metastatic cancer and:

- Is approved by the U.S. Food and Drug Administration (FDA);
- Is consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs and Biologics Compendium indication for the treatment of stage four advanced metastatic cancer; and
- Supported by peer-reviewed medical literature

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Step therapy

A form of **precertification** under which certain **prescription drugs** will be excluded from coverage, unless a first-line therapy drug(s) is used first by you. The list of step-therapy drugs is subject to change by **Aetna** or an affiliate. An updated

and
- In your prescriber's opinion, it is effective in treating your disease or condition

In addition, we will waive **step therapy** or fail-first protocol if the **step therapy prescription drug** is used to treat stage four advance metastatic cancer and:
- Is approved by the U.S. Food and Drug Administration (FDA);
- Is consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs and Biologics Compendium indication for the treatment of stage four advanced metastatic cancer; and
- Supported by peer-reviewed medical literature

HI SH HOC-2021 05 pg 106

Step therapy

A form of **precertification** under which certain **prescription drugs** will be excluded from coverage, unless a first-line therapy drug(s) is used first by you. The list of step-therapy drugs is subject to change by **Aetna** or an affiliate. An updated copy of the list of drugs subject to **step therapy** shall be available upon request by you or may be accessed on the **Aetna** website at www.aetna.com/formulary.

The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the

copy of the list of drugs subject to **step therapy** shall be available upon request by you or may be accessed on the **Aetna** website at www.aetna.com/formulary. The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions. Step Therapy protocols require that alternative drugs be tried first, when clinically warranted, and for a certain duration before the prescribed drug can be covered by a plan. A prior authorization or exceptions process is available when the protocol is not satisfied, to collect information so that coverage consistent with the conditions included by the ST protocol can be evaluated and coverage determined under the benefit. Messaging is provided to the dispensing pharmacy advising that the plan's ST protocols require alternative drugs first before the prescribed drug will be covered. The decision to implement step therapy is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the duration or quantity of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions. Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or	same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions. Step Therapy protocols require that alternative drugs be tried first, when clinically warranted, and for a certain duration before the prescribed drug can be covered by a plan. A prior authorization or exceptions process is available when the protocol is not satisfied, to collect information so that coverage consistent with the conditions included by the ST protocol can be evaluated and coverage determined under the benefit. Messaging is provided to the dispensing pharmacy advising that the plan's ST protocols require alternative drugs first before the prescribed drug will be covered. The decision to implement step therapy is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the duration or quantity of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions. Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug, and coverage conditions are not affected or altered by the medication's intended area

contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug, and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM Criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

MED/SURG drugs with Step Therapy:

(Below are examples of MED/SURG drugs with ST)

EXCHANGE FORMULARY
SymlinPen
Trulicity
Fosamax Plus D
Omnaris
Toviaz
Cardura XL
Savella
Aimovig
Emgality
Febuxostat
Lumigan
Zioptan

Aetna does not use generic substitution as part of the UM strategy for step therapy.

Pharmacy Quantity Limits (QL):

Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered for the drug, or the number of prescription claims for the drug over a period of utilization. For example, UM Criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

MH/SUD drugs with Step Therapy:

EXCHANGE FORMULARY
Desvenlafaxine ER
Fetzima cap/Pack
Trintellix
Viibryd tab/Pack
Vyvanse caps, chew

Aetna does not use generic substitution as part of the UM strategy for step therapy.

Pharmacy Quantity Limits:

Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered for the drug, or the number of prescription claims for the drug over a period of time. Pharmacy QLs are applied to each drug class regardless of whether the intended use is for a MH/SUD condition or a MED/SURG condition. Pharmacy QLs apply to both generic and brand drugs.

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Prescribing units

Some **prescription drugs** are subject to quantity limits. These quantity limits help your **prescriber** and pharmacist check that your **prescription drug** is used correctly and safely. We rely

of time. Pharmacy QLs are applied to each drug class regardless of whether the intended use is for a MH/SUD condition or a MED/SURG condition. Pharmacy QLs generally apply to both generic and brand drugs. HI SG HOC-2021 05 pg 51-52 **Prescribing units** Some **prescription drugs** are subject to quantity limits. These quantity limits help your **prescriber** and pharmacist check that your **prescription drug** is used correctly and safely. We rely on medical guidelines, FDA-approved recommendations and other criteria developed by us to set these quantity limits. The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions. Quantity Limits establish a maximum quantity of certain medications that will be covered by the client's plan over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered by the client for the dug, or the number of prescription claims for the drug over a period of time. When a member's claim exceeds the established limit for the drug, the claim will be rejected by the CVS Caremark processing system. Messaging is provided to the dispensing pharmacy advising that the plan's drug limitation has been exceeded or that a prior authorization is required for coverage of an additional quantity. The decision to implement quantity limit is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the quantity or duration of therapy needed by most patients. UM Criteria are developed based upon published	on medical guidelines, FDA-approved recommendations and other criteria developed by us to set these quantity limits. The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions. Quantity Limits establish a maximum quantity of certain medications that will be covered by the client's plan over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered by the client for the dug, or the number of prescription claims for the drug over a period of time. When a member's claim exceeds the established limit for the drug, the claim will be rejected by the CVS Caremark processing system. Messaging is provided to the dispensing pharmacy advising that the plan's drug limitation has been exceeded or that a prior authorization is required for coverage of an additional quantity. The decision to implement quantity limit is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the quantity or duration of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions. Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are

clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are written to effectively manage utilization and minimize cost associated with uses that are outside the scope of the plan's pharmacy benefit.

MED/SURG drugs with Quantity Limits:

(Below are examples of MED/SURG drugs with QL)

EXCHANGE FORMULARY

Descovy
Lamivudine
Viread
Harvoni
Sovaldi
Junel
Mirena
Norditropin
Onmaris
Fluticasone nasal spray
Omeprazole
Lansoprazole
Ondansetron
Granisetron

based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are written to effectively manage utilization and minimize cost associated with uses that are outside the scope of the plan's pharmacy benefit.

MH/SUD drugs with Quantity Limits:

(Below are examples of MED/SURG drugs with QL)

EXCHANGE FORMULARY

Alprazolam tabs, ODT
Chlordiazepoxide
Diazepam oral conc, oral soln, tabs
Lorazepam oral conc, tabs
Oxazepam
Desvenlafaxine ER
Fetzima caps, pack
Nuplazid caps, tabs
Hetlioz caps
Eszopiclone
Ramelteon
Temazepam
Amphetamine/Dextroamphetamine
Vyvanse
Atomoxetine
Dexmethylphenidate
Methylphenidate
Bupropion ER
Nicotrol oral inhaler, nasal spray
Varenicline
Buprenorphine/naloxone SL film
Zubsolv
Vivitrol injection

Aubagio Gilenya Oxycodone/Acetaminophen Tramadol Aimovig Emgality Lidocaine gel Synera patch	

B. Identify the factors used in the development of the limitation(s);

Factors: Prior Authorization:

Pharmacy Prior Authorization (PA)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Factors	• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability • Applicable lab values or other test results required for appropriate treatment • Appropriate medication uses for indications or conditions based on national guidelines • Use in appropriate patient populations • Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines • Potential for inappropriate or off-label use • Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met • Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies • Reduce waste, unnecessary drug use, fraud, or abuse	• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability • Applicable lab values or other test results required for appropriate treatment • Appropriate medication uses for indications or conditions based on national guidelines • Use in appropriate patient populations • Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines • Potential for inappropriate or off-label use • Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met • Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies • Reduce waste, unnecessary drug use, fraud, or abuse

Pharmacy Prior Authorization (PA)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Definitions of Factors	• **Patient safety concerns with a drug or drug class; unknown long-term safety or durability** – Imposing prior authorization based on this factor affords an opportunity to ensure that safety protocols are maintained. o **Evidentiary Standard**: Safety concerns noted by the manufacturer in clinical trials or in post-marketing reports o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Applicable lab values or other test results required for appropriate treatment –** Prior authorization may be imposed in order to ensure appropriate monitoring and testing in patient treatment o **Evidentiary Standard**: specific lab values or test results required for proper diagnosis or for determining response to therapy o **Sources**: published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care noted in in clinical literature, appropriate clinical drug information from other sources, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Appropriate medication uses for indications or conditions based on national guidelines; Use in appropriate patient populations –** National treatment guidelines and the FDA's evaluation of these drugs determine their safety and efficacy for a particular disease or illness within the intended population, and define the drug's use as initial therapy, second line therapy, or concurrent therapy. First line therapy refers to the initial recommended treatment for a disease or illness. o **Evidentiary Standard**: FDA-approved indications; recommended off-label uses o **Sources**: published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Potential for inappropriate or off-label use –** National treatment guidelines and the Food and Drug Administration's evaluation of these drugs determine their safety and efficacy for a particular disease or illness and define recommended duration of therapy o **Evidentiary Standard**: controlled substance status; reports of off label use o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug	

Pharmacy Prior Authorization (PA)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
	information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Opportunity for optimizing patient outcomes and to ensure treatment goals of the drug are being met** – Confirm patient is responding to therapy, e.g., A1C or cholesterol targets are being met. o **Evidentiary Standard**: improvement of symptoms from baseline; reduction of elevated blood levels (e.g., cholesterol) o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Requirement for additional treatment supportive therapies -** Additional supportive therapies, in addition to medications, may be recommended in the guidelines as the most effective treatment approach for a given condition. These therapies include but are not limited to behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies. o **Evidentiary Standard**: behavioral counseling, diet therapy o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Reduce waste, unnecessary drug use, fraud, or abuse**: practices that, directly or indirectly, result in unnecessary costs, overusing services. o **Evidentiary Standard**: complex treatment regimens requiring dose titration o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria	

Factors: Step Therapy:

Pharmacy Step Therapy (ST)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Factors	• Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands • Clinical safety and adverse events based on FDA approved labeling, national clinical guideline recommendations, and other evidentiary standards • Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards • Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms • Availability of therapeutic alternatives, including generics, used to treat the same condition	• Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands • Clinical safety and adverse events based on FDA approved labeling, national clinical guideline recommendations, and other evidentiary standards • Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards • Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms • Availability of therapeutic alternatives, including generics, used to treat the same condition
Definitions of Factors	• **Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands; Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms; Availability of therapeutic alternatives, including generics, used to treat the same condition:** A drug is considered lower cost when there are other recommended more cost effective alternatives, supported by the resources described below, for the treatment of the disease or illness o **Evidentiary Standard**: generics available to treat a condition; multiple safe and effective dosage forms or therapeutic alternatives available to treat a condition o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Clinical safety and adverse events based on FDA approved labeling, national clinical guideline recommendations, and other evidentiary standards:** Applying step therapy based on this factor affords an opportunity to ensure that appropriate dosing and safety protocols based on clinical practice are maintained. o **Evidentiary Standard**: Safety concerns noted by the manufacturer in clinical trials or in post-marketing reports	

Pharmacy Step Therapy (ST)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
	○ **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards**: National treatment guidelines and the FDA's evaluation of these drugs determine their safety and efficacy for a particular disease or illness and define the drug's use as initial therapy, second line therapy, or concurrent therapy. First line therapy refers to the initial recommended treatment for a disease or illness. ○ **Evidentiary Standard**: certain therapeutic classes are more effective in treating a condition ○ **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria	

Factors: Pharmacy Quantity Limits:

Pharmacy Quantity Limits (QL)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Factors	• Enhance patient safety ○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA ○ To promote appropriate drug dosing, including strength and frequency ○ To prevent overutilization ○ When abuse or misuse by the patient is possible ○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain • Cost and cost effectiveness	• Enhance patient safety ○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA ○ To promote appropriate drug dosing, including strength and frequency ○ To prevent overutilization ○ When abuse or misuse by the patient is possible ○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain • Cost and cost effectiveness

Pharmacy Quantity Limits (QL)		
	○ Prevention of overutilization ○ Discouragement of misuse and waste through dose efficiency QLs, which ensure that the appropriate tablet strength is utilized ○ Lack of documented efficacy/unknown efficacy at higher doses • Discourage misuse, waste, and abuse ○ Maximum daily dosing or maximum duration of use limits	○ Prevention of overutilization ○ Discouragement of misuse and waste through dose efficiency QLs, which ensure that the appropriate tablet strength is utilized ○ Lack of documented efficacy/unknown efficacy at higher doses • Discourage misuse, waste, and abuse ○ Maximum daily dosing or maximum duration of use limits
Definitions of Factors	• **Enhance patient safety:** Applying quantity limits based on this factor affords an opportunity to ensure that safety and treatment goals of the drug are being met: National treatment guidelines and the Food and Drug Administration's evaluation of these drugs determine their safety and efficacy for a particular disease or illness and define recommended duration of therapy ○ **Evidentiary Standard**: Safety concerns noted by the manufacturer in clinical trials or in post-marketing reports ○ **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Cost and cost effectiveness:** Excessive quantity is defined as a quantity that exceeds the recommended dosing regimen or the recommended duration of therapy. Quantity limits are based on FDA-approved indications, standard clinical practice, and guidelines: Dosing recommended treatment for a disease or illness. National treatment guidelines and the FDA's evaluation of these drugs determine the appropriate dosing based on safety and efficacy for a particular disease or illness. ○ **Evidentiary Standard**: lower-cost, safe and effective drugs available to treat a condition ○ **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Discourage misuse, waste, and** abuse: practices that, directly or indirectly, result in unnecessary costs, overusing services.	

Pharmacy Quantity Limits (QL)	
	○ **Evidentiary Standard**: many strengths available for a drug that requires individualized dosing ○ **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

PA FACTORS and SOURCES
MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
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J. Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee
MH/SUD SOURCES
A. US Food and Drug Administration (FDA) product labeling

PA FACTORS and SOURCES
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1.

Applicable lab values or other test results required for appropriate treatment

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B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
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2. Appropriate medication uses for indications or conditions based on national guidelines

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B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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3. Use in appropriate patient populations

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4. Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines

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5. Potential for inappropriate or off-label use

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6. Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met

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7. Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies

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B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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8. Reduce waste, unnecessary drug use, fraud, or abuse

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Pharmacy Step Therapy:

1. Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands

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B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
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H. Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
I. Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area
J. Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

2. Clinical safety and adverse events based on FDA approved labeling, national clinical guideline recommendations, and other evidentiary standards

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), US Food and Drug Administration (FDA), National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
G. Comparison of similar drugs in terms of safety and efficacy
H. Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
I. Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area
J. Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee
MH/SUD SOURCES
A. US Food and Drug Administration (FDA) product labeling

B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), FDA, National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
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3. Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
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F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), US Food and Drug Administration (FDA), National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
G. Comparison of similar drugs in terms of safety and efficacy

H. Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
I. Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area
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MH/SUD SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD
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4. Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex

D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), US Food and Drug Administration (FDA), National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
G. Comparison of similar drugs in terms of safety and efficacy
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MH/SUD SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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5. Availability of therapeutic alternatives, including generics, used to treat the same condition

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
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MH/SUD SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), FDA, National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
G. Comparison of similar drugs in terms of safety and efficacy

H. Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
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Pharmacy Quantity Limits:

1. Enhance patient safety

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
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C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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2. Cost and cost effectiveness

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
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G. Comparison of similar drugs in terms of safety and efficacy

H. Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
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C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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3. Discourage misuse, waste, and abuse

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex

D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), US Food and Drug Administration (FDA), National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
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C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
F. Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), FDA, National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ)
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When using the above factors to support application of prior authorization, step therapy or quantity limits to drugs, no more weight is given to one factor over another, and the UM is applied without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.
Limits are not imposed on pharmacy services 'as a whole' – this concept is not applicable to the pharmacy benefit. Prior Authorization, Step Therapy and Quantity Limits are not applied to the entire classification of prescription drugs, but only to certain identified drugs where the factors are applicable.

D. Identify the methods and analysis used in the development of the limitation(s); and

Prior Authorization, Step Therapy and Quantity Limits are not applied to the entire classification of prescription drugs, but only to certain identified drugs where the factors are applicable, as described below.

The methodology used in the development of CVS Caremark standard Utilization Management (UM) programs is the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions.

Methodology to determine whether to apply Pharmacy Prior Authorization to a drug:
The decision to develop prior authorization is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the duration or quantity of therapy needed by most patients, as well as evidence-based reviews of the medical literature and relevant clinical information. UM tools, including PA, should not cause delay of care or have an impact on, impede or prevent emergency or urgent access to medication. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s).

CVS Caremark utilizes the Clinical Program Oversight process for review and approval of any new criteria, updates, and annual review of utilization criteria and clinical program content. As part of this process, the UM or Clinical Program will be reviewed by one or more External Consultants, who are physicians practicing in the relevant clinical area. The CVS Caremark National P&T Committee is an external advisory body of expert members from a variety of medical specialties, who reviews and approves all UM criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling). CVS Caremark develops standard UM programs, and a health plan or client chooses which UM programs to include in the plan offering.

When using the above factors to support application of prior authorization to drugs, no more weight is given to one factor over another, and prior authorization is applied without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.

During the process of developing and assigning prior authorization to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable. These sources provide the background information used when considering the factors. The process includes the following steps:

- Clinical pharmacists in the Utilization Management Development team review clinical sources of information about indication, dosing, efficacy, strength, dosage forms and safety information to understand the drug's place in therapy and draft prior authorization criteria.
- The Formulary Review Committee (FRC) evaluates business factors affecting formulary prior authorization, such as utilization trends and plan sponsor cost. Drug utilization trend reports and applicable manufacturer agreements are cost information sources used when applying these factors. FRC considers of the lowest cost option for generic, biosimilar, and brand-name drugs and makes business recommendations to achieve lowest net cost. Cost-effectiveness is reviewed relative to alternatives in the same class, also considering its impact on members.
- Clinical literature including treatment guidelines are consulted about dosing, how the drug is used to treat the condition, side effects and safety profile, how it compares to other drugs available to treat the same condition and point out other concerns that may exist with the therapy.
- Drugs with known potential for abuse are considered for a prior authorization to promote their safe use.
- Drugs with evidence indicating that there is potential for harm or ineffectiveness in a population that can be defined by age are considered for a prior authorization to ensure that they are used in the appropriate population.
- Other safety concerns may be addressed by a prior authorization at the recommendation of the reviewing internal medical director or by the external clinical expert(s).
- All this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, the new drug is available in many different strengths, or does not have a defined recommended dose and can be used 'as needed', or may have potential for abuse or misuse, or age defines its use, then that drug may have a prior authorization applied to ensure appropriate use.
- These criteria are reviewed by internal clinical pharmacists, medical directors, and an additional external expert consultant before implementation, during the prior authorization maintenance and during the clinical oversight.
- By reviewing a range of disease states, the P&T Committee ensures that each criteria is consistent with clinical sources, and not discouraging enrollment by any group of enrollees.
- The P&T Committee ensures that drugs for the treatment of MH/SUD conditions are not managed more restrictively than drugs for other diseases.
- All the source information is reviewed as appropriate during annual review of criteria to determine if recommendations have changed in the past year. As part of this process, one or more external clinical experts will review the criteria again. Formulary prior authorization are updated as deemed necessary during this review, based on the same factors and sources.

- The P&T Committee votes on the adoption of presented formulary prior authorization, meets on a regular basis and not less frequently than quarterly, and conducts an annual review of all standard prior authorization. Formulary prior authorization criteria previously established are maintained and updated based on the same factors and using the most current version of the sources and/or evidentiary standards.

Methodology to determine whether to apply Pharmacy Step Therapy to a drug:
Step Therapy protocols require that alternative drugs be tried first, when clinically warranted, and for a certain duration before the prescribed drug can be covered by a plan. A prior authorization or exceptions process is available when the protocol is not satisfied, to collect information so that coverage consistent with the conditions included by the ST protocol can be evaluated and coverage determined under the benefit. Messaging is provided to the dispensing pharmacy advising that the plan's ST protocols require alternative drugs first before the prescribed drug will be covered.

The decision to implement step therapy is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the duration or quantity of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s).

CVS Caremark utilizes the Clinical Program Oversight process for review and approval of any new criteria, updates, and annual review of utilization criteria and clinical program content. As part of this process, the UM or Clinical Program will be reviewed by one or more External Consultants, who are physicians practicing in the relevant clinical area. The CVS Caremark National P&T Committee is an external advisory body of expert members from a variety of medical specialties, who reviews and approves all UM criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling). CVS Caremark develops standard UM programs, and a health plan or client chooses which UM programs to include in the plan offering.

When using the above factors to support application of step therapy to drugs, no more weight is given to one factor over another, and step therapy is applied without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.

During the process of developing and assigning step therapy to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable. These sources provide background information that is used when considering the factors. The process includes the following steps:

- Clinical pharmacists in the Utilization Management Development department use the clinical sources US Food and Drug Administration labeling, Centers for Medicare & Medicaid Services accepted drug compendia, published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies when using the factors of dose safety, dose optimization, and if a drug is commonly abuse or misused to draft step therapy.
- Clinical sources inform about dosing, how the drug is used to treat the condition, side effects and safety profile, how it compares to similar drugs and point out other concerns that may exist with the therapy.
- All of this information in the therapeutic drug class is considered. If all clinical attributes are equivalent, then the determination may be made to apply step therapy to the drug, requiring a trial of a more cost-effective drug that treats the same condition and has similar efficacy.
- The Formulary Review Committee (FRC) evaluates business factors affecting step therapy, such as utilization trends and plan sponsor cost. Drug utilization trend reports and applicable manufacturer agreements are cost information sources used when applying these factors. The lowest cost option for generic, biosimilar, and brand-name drugs is considered during tier recommendations to achieve lowest net cost. Cost-effectiveness is reviewed relative to alternatives in the same class, also considering its impact on members.
- Other safety concerns may be addressed by a step therapy program at the recommendation of the external clinical expert(s).
- By reviewing a range of disease states, the P&T Committee ensures that each step therapy is consistent with clinical sources, and not discouraging enrollment by any group of enrollees.
- The P&T Committee ensures that quantity limits for MH/SUD drugs are not managed more restrictively than drugs for other disease states.
- All the source information is reviewed as appropriate during annual review of step therapy criteria to determine if recommendations have changed in the past year. As part of this process, one or more external clinical experts will review the criteria again. Step therapies are updated as deemed necessary during this review, based on the same factors and sources.
- The P&T Committee votes on the adoption of presented step therapy, meets on a regular basis and not less frequently than quarterly, and conducts an annual review of all standard step therapies. Step therapy previously established are maintained and updated based on the same factors and using the most current version of the sources and/or evidentiary standards.

Methodology to determine whether to apply Pharmacy Quantity Limits to a drug:
The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions.

Quantity Limits establish a maximum quantity of certain medications that will be covered by the client's plan over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered by the client for the dug, or the number of prescription claims for the drug over a period of time. When a member's claim exceeds the established limit for the drug, the claim will be rejected by the CVS Caremark processing system. Messaging is provided to the dispensing pharmacy advising that the plan's drug limitation has been exceeded or that a prior authorization is required for coverage of an additional quantity.

The decision to implement quantity limit is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the quantity or duration of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are written to effectively manage utilization and minimize cost associated with uses that are outside the scope of the plan's pharmacy benefit.

CVS Caremark utilizes the Clinical Program Oversight process for review and approval of any new criteria, updates, and annual review of utilization criteria and clinical program content. As part of this process, the UM or Clinical Program will be reviewed by one or more External Consultants, who are physicians practicing in the relevant clinical area. The CVS Caremark National P&T Committee is an external advisory body of expert members from a variety of medical specialties, who reviews and approves all UM criteria (i.e., prior authorization, step therapy and quantity limits outside of FDA-approved labeling). The P&T Committee reviews and approves for QLs that are outside of the FDA label and clinical appropriateness coverage criteria for QLs. CVS Caremark develops standard UM programs, and a health plan or client chooses which UM programs to include in the plan offering.

When using the above factors to support application of quantity limits to drugs, no more weight is given to one factor over another, and quantity limits are applied without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.

During the process of developing and assigning quantity limits to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable. These sources provide the background information used when considering the factors. The process includes the following steps:

- Clinical pharmacists in the Utilization Management Development department use the clinical sources US Food and Drug Administration labeling, Centers for Medicare & Medicaid Services accepted drug compendia, published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies when using the factors of dose safety, dose optimization, and if a drug is commonly abuse or misused to draft quantity limits.
- Quantity limits used for dose optimization are considered since they may simplify a medication regimen which can help improve adherence to the prescribed drug regimen, reducing the number of doses required and often leading to more cost-effective drug use.
- A drug may have a known potential for abuse or misuse and the use of quantity limits may be warranted to promote their safe use.

- All of this information is utilized to determine whether a quantity limit is appropriate for the drug. If, for example, the new drug is available in many different strengths, or does not have a defined recommended dose and can be used 'as needed', or may have potential for abuse or misuse, then that drug may have a quantity limit applied to ensure an appropriate amount is allowed per prescription.
- The Formulary Review Committee (FRC) evaluates business factors affecting the quantity limits, such as utilization trends and plan sponsor cost. Drug utilization trend reports and applicable manufacturer agreements are cost information sources used when applying these factors. The lowest cost option for generic, biosimilar, and brand-name drugs is considered during tier recommendations to achieve lowest net cost. Cost-effectiveness is reviewed relative to alternatives in the same class, also considering its impact on members.
- Other safety concerns may be addressed by a quantity limit program at the recommendation of the reviewing external clinical expert(s).
- By reviewing a range of disease states, the P&T Committee ensures that each quantity limit is consistent with clinical sources, and not discouraging enrollment by any group of enrollees.
- The P&T Committee ensures that quantity limits for MH/SUD drugs are not managed more restrictively than drugs for other disease states.
- All the source information is reviewed as appropriate during annual review of quantity limit criteria to determine if recommendations have changed in the past year. As part of this process, one or more external clinical experts will review the criteria again. Quantity limits are updated as deemed necessary during this review, based on the same factors and sources.
- The P&T Committee votes on the adoption of presented quantity limits, meets on a regular basis and not less frequently than quarterly, and conducts an annual review of all standard quantity limits. Quantity limits previously established are maintained and updated based on the same factors and using the most current version of the sources and/or evidentiary standards.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

Pharmacy Prior Authorization (PA) Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

PRIOR AUTHORIZATION (PA) ANALYSIS								
Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021								
Category		Analysis						
Medical / Surgical	Medical / Surgical	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	TOTAL Drug Count by Tier	72	985	137	157	199	196	1,746

	PA Drug Count by Tier	0	67	10	17	190	196	480
	% of Total PA Drugs by Tier	0.0%	14.0%	2.1%	3.5%	39.6%	40.8%	
	% MED/SURG Drugs with PA	0.0%	6.8%	7.3%	10.8%	95.5%	100.0%	**27.5%**
Mental Health	**Mental Health**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	0	115	2	12	0	3	132
	PA Drug Count by Tier	0	0	0	3	0	3	6
	% of Total PA Drugs by Tier	0.0%	0.0%	0.0%	50.0%	0.0%	50.0%	
	% MH Drugs with PA		0.0%	0.0%	25.0%	0.0%	100.0%	**4.5%**
Substance Use Disorder	**Substance Use Disorder**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	4	6	1	0	2	0	13
	PA Drug Count by Tier	0	1	0	0	0	0	1
	% of Total PA Drugs by Tier	0.0%	100.0%	0.0%	0.0%	0.0%	0.0%	
	% SUD Drugs with PA	0.0%	16.7%	0.0%	0.0%	0.0%	0.0%	**7.7%**

* Note: Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of administration

Comparative Analysis for pharmacy prior authorization Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

When the factors for pharmacy prior authorization are considered consistently across all drugs and drug classes, the outcome shows that prior authorization is applied to a lower percentage of drugs in the MH and SUD drug categories compared to MED/SURG drug category. Pharmacy prior authorization is applied to:

- 27.5% (480 out of 1,746) of the drugs in the Medical/Surgical category
- 4.5% (6 out of 132) of the drugs in the Mental Health category
- 7.7% (1 out of 13) of the drugs in the Substance Use Disorder category

The development of prior authorization UM programs is based on comparable processes, strategies, evidentiary standards, and factors, for therapeutic drug classes used to treat MH, SUD, and MED/SURG conditions. CVS Caremark develops standard prior authorization UM programs, and a client or health plan chooses which prior authorization programs to include in the plan offering. The development of prior authorization is based on the factors below.

The MH/SUD drug classes are listed below, showing the prior authorization in each drug class for this plan:

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MH/SUD DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTIANXIETY		19	0	0%
ANTIDEPRESSANTS Emsam	> Patient safety concerns exist/Unknown long-term safety or durability > Appropriate medication uses based on national guidelines > Use in appropriate patient populations	47	1	2%
ANTIPSYCHOTICS Latuda Nuplazid caps, tabs	> Appropriate medication uses based on national guidelines > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	35	3	9%
HYPNOTICS Belsomra Hetlioz	> Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use	10	2	20%
ADHD		21	0	0%
SUD Acamprosate DR	> Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use > Requirement for additional treatment supportive therapies	13	1	8%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown

Comparable MED/SURG drug classes are listed below, showing the prior authorization in the comparable drug classes for this plan:

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTIVIRALS - HEPATITIS C	> Appropriate medication uses based on national guidelines > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	23	18	78%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTINEOPLASTIC & ADJUNCTIVE THERAPIES	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	136	109	80%
OSTEOPOROSIS AGENTS	> Patient safety concerns exist/Unknown long-term safety or durability > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	13	6	46%
GROWTH HORMONE	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use	15	15	100%
GI - PANCREATIC ENZYMES	> Appropriate medication uses based on national guidelines > Use in appropriate patient populations	4	4	100%
ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	> Patient safety concerns exist/Unknown long-term safety or durability > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations	3	3	100%
MULTIPLE SCLEROSIS AGENTS	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	30	30	100%
ANALGESICS - OPIOID	> Use in appropriate patient populations > Potential for inappropriate, off-label use > Reduce waste, unnecessary drug use, fraud or abuse	47	43	91%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANALGESICS - ANTI-INFLAMMATORY	> Patient safety concerns exist/Unknown long-term safety or durability > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	53	29	55%
DERM - ANTIPSORIATICS	> Patient safety concerns exist/Unknown long-term safety or durability > Use in appropriate patient populations	20	16	80%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown

Step Therapy (ST) Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

STEP THERAPY ANALYSIS								
Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021								
Category		**Analysis**						
Medical / Surgical	**Medical / Surgical**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	72	985	137	157	199	196	1,746
	ST Drug Count by Tier	0	11	14	23	0	0	48
	% of Total ST Drugs by Tier	0.0%	22.9%	29.2%	47.9%	0.0%	0.0%	
	% MED/SURG Drugs with ST	0.0%	1.1%	10.2%	14.6%	0.0%	0.0%	**2.7%**
Mental Health	**Mental Health**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	0	115	2	12	0	3	132
	ST Drug Count by Tier	0	1	0	8	0	0	9
	% of Total ST Drugs by Tier	0.0%	11.1%	0.0%	88.9%	0.0%	0.0%	
	% MH Drugs with ST	0.0%	0.9%	0.0%	66.7%	0.0%	0.0%	**6.8%**

Substance Use Disorder	Substance Use Disorder	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	4	6	1	0	2	0	13
	ST Drug Count by Tier	0	0	0	0	0	0	0
	% of Total ST Drugs by Tier	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
	% SUD Drugs with ST	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**

* Note: Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration

Comparative Analysis for step therapy Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

When the factors for step therapy are considered consistently across all drugs and drug classes, the outcome shows that step therapy is applied to a comparable and small percentage of drugs in the MH and MED/SURG drug categories, and there is not step therapy applying to any drugs in the SUD drug category. Step therapy is applied to:

- 2.7% (48 out of 1,746) of the drugs in the Medical/Surgical category
- 6.8% (9 out of 132) of the drugs in the Mental Health category
- None of the drugs in the Substance Use Disorder category

The development of step therapy is based on comparable processes, strategies, evidentiary standards, and factors, for therapeutic drug classes used to treat MH, SUD, and MED/SURG conditions. CVS Caremark develops standard step therapy programs, and a client or health plan chooses which step therapy programs to include in the plan offering. The development of step therapy is based on the factors below.

The MH/SUD drug classes are listed below, showing the step therapy programs in each drug class for this plan:

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MH/SUD DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIANXIETY		19	0	0%
ANTIDEPRESSANTS Desvenlafaxine ER Fetzima cap/Pack Trintellix Viibryd tab/Pack	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	47	6	13%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MH/SUD DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIPSYCHOTICS Rexulti	> Promote use of most cost-effective products (generics and/or lower cost brands) > Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms > Alternatives available in the drug class (including generics) used to treat the same condition	35	1	3%
HYPNOTICS		10	0	0%
ADHD Vyvanse caps, chew	> Promote use of most cost-effective products (generics and/or lower cost brands) > Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms > Alternatives available in the drug class (including generics) used to treat the same condition	21	2	10%
SUD		13	0	0%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown

Comparable MED/SURG drug classes are listed below, showing the step therapy programs in the comparable drug classes for this plan:

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIDIABETICS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	56	24	43%
OSTEOPOROSIS AGENTS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	13	1	8%
NASAL AGENTS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	8	1	13%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
URINARY ANTISPASMODICS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	12	1	8%
GU - BPH	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	7	1	14%
FIBROMYALGIA AGENTS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	2	2	100%
MIGRAINE PRODUCTS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms > Alternatives available in the drug class (including generics) used to treat the same condition	23	6	26%
GOUT AGENTS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	5	1	20%
OPHTHALMIC AGENTS - GLAUCOMA	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	18	2	11%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown

Quantity Limits (QL) Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

QUANTITY LIMITS (QL) ANALYSIS								
Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021								
Category		**Analysis**						
Medical / Surgical	**Medical / Surgical**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	72	985	137	157	199	196	1,746
	QL Drug Count by Tier	55	217	51	17	188	191	719
	% of Total QL Drugs by Tier	7.6%	30.2%	7.1%	2.4%	26.1%	26.6%	
	% MED/SURG Drugs with QL	76.4%	22.0%	37.2%	10.8%	94.5%	97.4%	**41.2%**

	Mental Health	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
Mental Health	Total Drug Count by Tier	0	115	2	12	0	3	132
	QL Drug Count by Tier	0	37	2	4	0	3	46
	% of Total QL Drugs by Tier	0.0%	80.4%	4.3%	8.7%	0.0%	6.5%	
	% MH Drugs with QL	0.0%	32.2%	100.0%	33.3%	0.0%	100.0%	**34.8%**
	Substance Use Disorder	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
Substance Use Disorder	Total Drug Count by Tier	4	6	1	0	2	0	13
	QL Drug Count by Tier	4	1	1	0	1	0	7
	% of Total QL Drugs by Tier	57.1%	14.3%	14.3%	0.0%	14.3%	0.0%	
	% SUD Drugs with QL	100.0%	16.7%	100.0%	0.0%	50.0%	0.0%	**53.8%**

* Note: Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration

Comparative Analysis for Quantity Limits Small Group Exchange 2021 Formulary – Pharmacy Benefit Plan

When the factors for quantity limits are considered consistently across all drugs and drug classes, the outcome shows that quantity limits are applied to a varying percentage of drugs across the MH, SUD, and MED/SURG drug categories. Quantity limits are applied to:

- 41.2% (719 out of 1,746) of the drugs in the Medical/Surgical category.
- 34.8% (46 out of 132) of the drugs in the Mental Health category.
- 53.8% (7 out of 13) of the drugs in the Substance Use Disorder category.

The development of quantity limits is based on comparable processes, strategies, evidentiary standards, and factors, for therapeutic drug classes used to treat MH, SUD, and MED/SURG conditions. CVS Caremark develops standard quantity limit UM programs, and a client or health plan chooses which quantity limit programs to include in the plan offering. The development of quantity limits is based on the factors below.

The MH/SUD drug classes are listed below, showing the quantity limits in each drug class for this plan:

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MH/SUD DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
ANTIANXIETY Alprazolam tabs, Intensol	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)	19	13	68%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MH/SUD DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
oral conc, oral susp, ODT Chlordiazepoxide Clorazepate Diazepam oral conc, oral soln, tabs Lorazepam oral conc, tabs Oxazepam	> Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)			
ANTIDEPRESSANTS Desvenlafaxine ER Fetzima cap/Pack	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	47	3	6%
ANTIPSYCHOTICS Nuplazid caps, tabs	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	35	2	6%
HYPNOTICS Eszopiclone Hetlioz Ramelteon Temazepam Triazolam Zaleplon Zolpidem tab, ER tab	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	10	8	80%
ADHD Includes controlled substance drugs used to treat ADHD.	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	21	20	95%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MH/SUD DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
SUD Bupropion ER Nicotrol Oral Inhaler Nicotrol Nasal Spray Varenicline Buprenorphine/Naloxone SL Zubsolv Vivitrol inj	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	13	7	54%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown

Comparable MED/SURG drug classes are listed below, showing the quantity limits in the comparable drug classes for this plan:

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
ANTIVIRALS - HIV	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	60	60	100%
ANTIVIRALS - HEPATITIS C	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	23	23	100%
CONTRACEPTIVES	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	55	55	100%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
GROWTH HORMONE	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS)	15	15	100%
NASAL AGENTS	> Prevent overutilization (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)	8	7	88%
GI AGENTS - PPIs	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)	7	7	100%
ANTIEMETICS - 5-HT3	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	5	5	100%
MULTIPLE SCLEROSIS AGENTS	> Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	30	30	100%
ANALGESICS - OPIOID	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)	47	43	91%

State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
	> Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)			
MIGRAINE AGENTS	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)	23	21	91%
DERM - POST-HERPETIC NEURALGIA	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	7	6	86%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown

It is important to note, the MH and SUD categories include a limited number of drugs that are used to treat specific conditions considered as MH/SUD conditions. However, the M/S drug category encompasses drugs used to treat specific medical or surgical conditions, as well as all other products included in the pharmacy benefit formulary that are not classified as MH or SUD. The products classified in the M/S drug category, therefore, may also include items such as vaccines, vitamins, insulin syringes and needles, and antibiotics, which are not appropriate comparisons to the drugs that are used to treat anxiety, ADHD, opioid use disorder or tobacco use disorder, for example. The inclusion of these types of drugs in the calculation of the rate of quantity limits in the MED/SURG category may result in a total that appears lower than it would be if it only included comparable drugs used to treat chronic conditions like HIV, hepatitis-C, and multiple sclerosis, for example.

The methodology used in the analysis included comparing the percent of PA, ST, QL at the drug class level in order to achieve a more focused and appropriate comparison. The results include of ALL of the MH/SUD classes since they are the focus of the analysis and it is important to see how each NQTL affects all of those classes. Comparable MED/SURG classes, as defined by clinical pharmacists doing the analysis, are those that treat

conditions that require long-term therapy and have a similar or greater magnitude of the NQTL as seen in the MH/SUD classes, as opposed to classes that are categorized as M/S but are actually made up of other items as described above.

As described above, comparable M/S classes, are those that treat conditions that require long-term therapy and have a similar or greater magnitude of the NQTL as seen in the MH/SUD classes. MH/SUD classes remain the same for each NQTL because they are the only classes in that category. It would not be practical to include each and every M/S drug class in the results (as is done in the MH/SUD classes) due to the volume of drugs and classes in that category, so only a sample of classes are shown. The comparable M/S classes are not the same in each NQTL because the classes that are listed for PA, for example, may not be appropriate for ST due to the make-up of drugs that are available in the class, the conditions they treat, and the factors. For example, on the formulary, 9% of the Antipsychotics class has PA but there is one drug with ST in the class. The drugs requiring PA are brands that did not have a generic available in 2021, and are indicated for use in specific populations or as adjunct therapy. Prior authorization is appropriate for these drugs to ensure they are being used for the right patients in the right situations, but requiring a trial of previous therapy is less applicable in this class. Similarly, the M/S class of Antineoplastics has PA on 80% of the drugs, since it is important to ensure the right drug for the right patient and situation, but there is no ST in the class since that approach is not appropriate in cancer treatment.

Findings and Conclusion for Pharmacy Services: The analysis reveals that decisions about applying Prior Authorization, Step Therapy and Quantity Limit NQTLs follow the same process when rendered for MH/SUD drugs or M/S drugs. The conclusion that the processes, strategies, evidentiary standards, and factors used to apply PA, ST and QL to MH/SUD drugs are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, and factors used to apply PA, ST and QL to M/S drugs is based on the results shown.

The written materials analysis revealed that as written factors and standards used for applying PA to drugs are the same and are not used differently or more restrictively based on a drug being for M/S or MH/SUD treatment. The review of the P&T Committee minutes showing the decisions made for the period of 2021-2022 revealed that no decisions were made regarding PA for MH or SUD drugs during that timeframe.

An analysis of the formulary data showed that the M/S category had a higher percentage of drugs requiring PA than MH or SUD:

Drugs requiring PA – Exchange Formulary – 2021

- 27.5% (480 out of 1,746) of the drugs in the Medical/Surgical category
- 4.5% (6 out of 132) of the drugs in the Mental Health category
- 7.7% (1 out of 13) of the drugs in the Substance Use Disorder category

Further analysis was added in Step 5 as requested by MIA and did not reveal that the process is followed more stringently. The analysis by the PBM clinician noted that processes of tier placement and UM development are done independently and one does not rely on or relate to the other. PA is not applied to drugs with the goal of staying above or below a threshold within a given tier. The drugs that have PA were reviewed and the PBM clinician found that it is appropriate for those drugs to require PA based on the factors noted in the response to MIA 50 (a).

The written materials analysis revealed that as written factors and standards used for applying ST to drugs are the same and are not used differently or more restrictively based on a drug being for M/S or MH/SUD treatment. The review of the minutes showing the decisions made for the period of 2021-2022 revealed that the decision to apply ST to the M/S drug Qulipta and the MH drug Ambien followed a consistent process. Also, the analysis of the factors and the level of evidence for the sources used to inform the factors, as written in the policies show a consistent process. The sources of information are not explicit in the minutes but the PBM clinician analyzing the decisions can find the sources and standards as described in the process and assess that the process was followed consistently.

An analysis of the formulary data showed that step therapy is applied to a small percentage of drugs in the MH drug category and the MED/SURG drug category, and there is no step therapy applying to any drugs in the SUD drug category, as below:

Drugs requiring ST – Exchange Formulary – 2021

- 2.7% (48 out of 1,746) of the drugs in the Medical/Surgical category
- 6.8% (9 out of 132) of the drugs in the Mental Health category
- None of the drugs in the Substance Use Disorder category

Further analysis was added in Step 5 as requested by MIA and did not reveal that the process is followed more stringently. While the rate of ST in MH drugs is two times rate of ST in M/S drugs a comparison of percentages alone does not provide a complete view. As noted above, the analysis of the minutes revealed that no decisions were made to apply ST to MH/SUD, and the decisions for M/S drugs showed a consistent process of applying the factors and utilizing sources with comparable levels of evidence. Also, the analysis by the PBM clinician noted that processes of tier placement and UM development are done independently, and one does not rely on or relate to the other. ST is not applied to drugs with the goal of staying above or below a threshold within a given tier. The drugs that have ST on both formularies were reviewed and the PBM clinician found that it is appropriate for those drugs to require ST based on the factors noted in the response to MIA 50 (b).

The written materials analysis revealed that as written factors and standards used for applying QL to drugs are the same and are not used differently or more restrictively based on a drug being for M/S or MH/SUD treatment. The review of the minutes showing the decisions made for the period of 2021-2022 revealed that the decision to apply QL to the M/S drug Apokyn and the MH drug Qelbree followed a consistent process. Also, the analysis of the factors and the level of evidence for the sources used to inform the factors, as written in the policies show a consistent process. The sources of information are not explicit in the minutes but the PBM clinician analyzing the decisions can find the sources and standards as described in the process and assess that the process was followed consistently.

An analysis of the formulary data showed that quantity limits are applied to:

Drugs requiring QL – Exchange Formulary – 2021

- 41.2% (719 out of 1,746) of the drugs in the Medical/Surgical category.
- 34.8% (46 out of 132) of the drugs in the Mental Health category.

- 53.8% (7 out of 13) of the drugs in the Substance Use Disorder category.

Further analysis was added in Step 5 as requested by MIA and did not reveal that the process is followed more stringently. As mentioned in the response to MIA 50) (b) i., the M/S drug category encompasses drugs used to treat specific medical or surgical conditions, as well as all other products included in the pharmacy benefit formulary that are not classified as MH or SUD, which may include items such as vaccines, vitamins, insulin syringes and needles, and antibiotics. Since these items are not appropriate comparisons to the drugs that are used to treat anxiety, ADHD, opioid use disorder or tobacco use disorder, for example, but they are still included in the denominator for the M/S category, the rate of QL applying to this category is not a direct reflection of comparable drugs.

Nonetheless, as noted above, the analysis of the minutes revealed that decisions made to apply QL to M/S and MH/SUD drugs showed a consistent process of applying the factors and utilizing sources with comparable levels of evidence. It is important to note that 4 of the 6 MH/SUD classes contain controlled substances (Antianxiety, Hypnotics, ADHD, SUD; ranging from 26%-86% of the class) therefore, a higher percentage of these drugs have QL. In the SUD class, 7 of the 13 SUD drugs have QL and are indicated for tobacco use disorder or opioid use disorder where dosing is titrated often, so it is important to monitor the amount used by the patient.

The drugs that have QL on both formularies were reviewed and the PBM clinician found that it is appropriate for those drugs to require QL based on the factors noted in the response to MIA 50 (c).

Also, the analysis of the factors and the level of evidence used for the sources used to inform the factors, in operations show a consistent process. No unique process exists that is different in any way to apply the factors; sources used are different and drug/disease-specific. This analysis was done by PBM Clinicians, they are pharmacists, and they made no recommendations regarding NQTLs applied to MH/SUD and M/S drugs. No variation in the use of PBM Clinicians for MH/SUD compared to M/S NQTL analyses.

7. **Prescription Drug Formulary Design**

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Formulary Tiering and Design:
Aetna delegates the formulary tiering and design to CVS Caremark. The formulary, also called drug guide, is developed and managed through the activities of CVS Caremark National Pharmacy and Therapeutics (P&T) Committee (P&T Committee) and the Formulary Review Committee (FRC). Formulary decisions are made first as recommendations for additions and deletions voted on by FRC and then these recommendations are forwarded to the P&T Committee for final review and approval. Disciplines, involved in the formulary decision for medications to treat medical, mental health, substance use disorder and medical/surgical conditions included in these committees are pharmacists, physicians, and specialty physicians (allergists, cardiology, endocrinology, family practice, neurology, infectious disease, gerontology, gastroenterology, medical ethics, neurology, psychiatrists, hematology/oncology, pharmacology, and rheumatology). There is no separate formulary for medications to treat medical, mental health, and substance use disorder conditions, and there is no separate process of formulary design for medications to treat medical, mental health, and substance use disorder conditions. Accordingly, there is no mention of a separate formulary for medications to treat medical, mental health, and substance use disorder conditions in the Aetna Health Rider prescription drug plan member information documents. There is no separate committee making decisions only for medications to treat medical, mental health, substance use disorder and medical/surgical conditions. The P&T Committee reviews medications from a purely clinical perspective and does not have access to nor does it consider any information on rebates, negotiated discounts or net costs. FRC makes business recommendations evaluating factors such as utilization trends, impact of generic drugs or drugs designated to become available over the counter, brand sand generic pipeline, line of business, plan sponsor cost, applicable manufacturer agreement, potential impact on members. CVS Caremark works to include the most cost-effective drugs on the drug list. The above processes are used when making formulary decisions for all drug classes including drugs used for MH/SUD and MED/SURG conditions.

Cost-control measures: When drug classes have multiple generic and low-cost brand-name options that cover the same indications as more costly brand-name options in the same class, and the generic and low-cost brand-name options offer similar efficacy and safety. **Therapeutic alternatives** in formulary design: since many brand-name drugs do not provide clear clinical and/or financial advantages when compared to available drug options within the therapeutic class, several strategies are available to promote cost-effective use of medications ranging from tiered copays, excluding products from coverage or having a closed plan design.

- Tiered copays encourage members to use preferred formulary drugs.
- Products not included in the formulary have therapeutic alternatives available that deliver cost savings and are covered in the formulary.

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9. Outpatient prescription drugs

What you need to know about your outpatient prescription drug covered benefits

Read this section carefully so that you know:

- How to access **network pharmacies**
- **Eligible health services** under your plan
- Other services
- How you get an emergency **prescription** filled
- Where your schedule of benefits fits in
- What **precertification** requirements apply
- How can I request a medical exception
- Prescribing units

Some **prescription drugs** may not be covered or coverage may be limited. This does not keep you from getting **prescription drugs** that are not **covered benefits**. You can still fill your **prescription**, but you have to pay for it yourself. For more information see the schedule of benefits.

A **pharmacy** may refuse to fill a **prescription** order or refill when in the professional judgment of the pharmacist the **prescription** should not be filled.

Your plan provides standard safety checks to encourage safe and appropriate use of medications. These checks are intended to avoid adverse events and align with the medication's FDA-approved prescribing information and current published clinical guidelines and treatment standards. These checks are routinely updated as new medications come to market and as guidelines and standards are updated.

How to access network pharmacies

How do you find a network pharmacy?

You can find a **network pharmacy** online or by phone. See the *How to contact us for help* section for details.

You may go to any of our **network pharmacies**. If you do not get your **prescriptions** at a **network pharmacy**, your **prescriptions** will not be covered as **eligible health services** under the plan. See the *How you get an emergency prescription filled* section for **prescriptions** in an emergency or urgent care situation, or traveling outside of the plan's **service area**. **Pharmacies** include network **retail**, **mail order** and **specialty pharmacies**.

What if the pharmacy you have been using leaves the network?

Sometimes a **pharmacy** might leave the network. If this happens, you will have to get your **prescriptions** filled at another **network pharmacy**. You can use your **provider directory** or call the number on your ID card to find another **network pharmacy** in your area.

Eligible health services under your plan

Eligible health services include any **pharmacy** service that meets these three requirements:

- They are listed in the *Eligible health services under your plan* section.
- They are not listed in the *Exceptions* section.
- They are not beyond any limits in the schedule of benefits.

Your **pharmacy** services are covered when you follow the plan's general rules:

- You need a **prescription** from your **prescriber**.
- Your drug needs to be **medically necessary**. See the *Medical necessity, referral and precertification requirements* section.
- You need to show your ID card to the **pharmacy** when you get a **prescription** filled.

Your outpatient **prescription drug** plan is based on the drugs in the **drug guide**. The **drug guide** includes both **brand-name prescription drugs** and **generic prescription drugs**. Your pharmacist may substitute **generic prescription drugs** for **brand-name prescription drugs**. Your out-of-pocket costs may be less if you use a **generic prescription drug** when available. If a **prescription drug** is moved to a higher tier and there is no equivalent **prescription drug** in the lower tier you may get the **prescription drug** at the lower tier cost shares. You can call us at the number on your ID card or log on to your Aetna member website at www.aetna.com to see if a **prescription drug** that is not listed on the **drug guide** is covered.

Important note:

You may qualify for a medical exception if your **prescriber** determines that there is no equivalent **prescription drug** or device covered in the **drug guide** or the equivalent is ineffective in treating the disease or condition, or has caused or is likely to cause an adverse reaction or harm. Your **prescriber** may request a medical exception and submit the exception to us.

We reserve the right to include only one manufacturer's product on the **drug guide** when the same or similar drug (that is, a drug with the same active ingredient), supply or equipment is made by two or more different manufacturers.

We reserve the right to include only one dosage or form of a drug on the **drug guide** when the same drug (that is, a drug with the same active ingredient) is available in different dosages or forms from the same or different manufacturers. The product in the dosage or form that is listed on our **drug guide** will be covered at the applicable **copayment** or **coinsurance**.

Prescription drugs covered by this plan are subject to misuse, waste and/or abuse utilization review by us, your **provider** and/or your **network pharmacy**. The outcome of this review may include:

- Limiting coverage of the applicable drug(s) to one prescribing **provider** and/or one **network pharmacy**
- Limiting the quantity, dosage or day supply
- Requiring a partial fill or denial of coverage

Your **prescriber** may give you a **prescription** in different ways, including:

- Writing out a **prescription** that you then take to a **network pharmacy**
- Calling or e-mailing a **network pharmacy** to order the medication
- Submitting your **prescription** electronically

Once you receive a **prescription** from your **prescriber**, you may fill the **prescription** at a network **retail**, **mail order** or **specialty pharmacy**.

Partial fill dispensing program

Our program allows only a partial fill of your **prescription** through a **network pharmacy**. We will apply a prorated daily cost-share rate for a partial supply of a **prescription drug** if:

- The dispensing of the partial supply of a **prescription drug** is in your best interest
- The **prescription drug** is anticipated to be required for 3 months or more
- You request or agree to a partial supply for the purpose of synchronizing the dispensing of your **prescription drugs**
- The **prescription drug** is not a Schedule II controlled dangerous substance
- All prior authorization and utilization management requirements specific to the **prescription drug** at the time of synchronized dispensing are met

Any dispensing fees will not be prorated for dispensing a partial supply of a prescription drug or for the pharmacy synchronizing your **prescriptions**.

Retail pharmacy

Retail pharmacies may be used to obtain a supply of **prescription drugs**. You should show your ID card to the **network pharmacy** every time you get a **prescription** filled. The **network pharmacy** will submit your claim. You will pay any cost sharing directly to the **network pharmacy**.

You do not have to complete or submit claim forms. The **network pharmacy** will take care of claim submission.
See the schedule of benefits for details on supply limits and cost sharing.

Mail order pharmacy
Generally, the drugs available through mail order are maintenance drugs that you take on a regular basis for a chronic or long-term medical condition.
Outpatient **prescription drugs** are covered when dispensed by a network **retail** or **mail order pharmacy**.

Specialty pharmacy
Specialty prescription drugs are covered when dispensed through a network **retail** or **specialty pharmacy**.

Specialty prescription drugs typically include high-cost drugs that require special handling, special storage or monitoring and include but are not limited to oral, topical, inhaled and injected ways of giving them. You can access the list of **specialty prescription drugs**. See the *How to contact us for help* section for how.

The initial **prescription** for **specialty prescription drugs** must be filled at a network **retail** or **specialty pharmacy**.

Specialty prescription drugs may fall under various drug tiers regardless of their names. See the schedule of benefits for details on supply limits and cost sharing.

Other services
[Preventive contraceptives
Your outpatient **prescription drug** plan covers certain drugs and devices that the U.S. Food and

Drug Administration (FDA) has approved to prevent pregnancy when prescribed by a **prescriber** and the **prescription** is submitted to the pharmacist for processing. Your outpatient **prescription drug** plan also covers related services and supplies needed to administer covered devices. For females who are able to become pregnant, your outpatient **prescription drug** plan covers certain drugs and devices that the U.S. Food and Drug Administration (FDA) has approved to prevent pregnancy when prescribed by a **prescriber** and the **prescription** is submitted to the pharmacist for processing. Your outpatient **prescription drug** plan also covers related services and supplies needed to

administer covered devices. In each of the methods, at least one form of therapeutically equivalent contraception identified by the FDA is included. You can access the list of contraceptive drugs. See the *How to contact us for help* section for how.

We cover over-the-counter (OTC) without a **prescription** and **generic prescription drugs** and devices for each category identified by the FDA at no cost share. If a **generic prescription drug** or device is not available within a therapeutically equivalent category, you may obtain certain **brand-name prescription drugs** or devices for that method at no cost share.

Diabetic supplies

Eligible health services include but are not limited to the following diabetic supplies upon **prescription** by a **prescriber**:

Important note:

You may qualify for a medical exception if your provider determines that the contraceptives covered standardly as preventive are not medically appropriate or not on the formulary but are **medically necessary** for you to adhere to the appropriate use of the contraceptives. Your **prescriber** may request a medical exception and submit the exception to us.**]**

- Diabetic needles, syringes and pens
- Test strips – blood glucose, ketone and urine
- Blood glucose calibration liquid
- Lancet devices and kits
- Alcohol swabs
- Continuous glucose monitors
- Insulin infusion disposable pumps

See the *Specific conditions - Diabetic equipment, supplies, treatment and education* section for coverage of blood glucose meters and insulin pumps and for diabetic supplies that you can get from other **providers**.

Off-label use

U.S. Food and Drug Administration (FDA) approved **prescription drugs** may be covered when the off- label use of the drug has not been approved by the FDA for your symptom(s). Eligibility for coverage is subject to the following:

- The drug must be accepted as safe and effective to treat your symptom(s) in any authoritative compendia as recognized periodically by the Federal Secretary of Health and Human Services or the Commissioner

Health care services related to off-label use of these drugs may be subject to **precertification**, **step therapy** or other requirements or limitations.

Oral infertility drugs

Eligible health services include charges for oral **infertility prescription drugs** used for the purpose of treating **infertility**.

Orally administered anti-cancer drugs, including chemotherapy drugs

Eligible health services include any drug prescribed for the treatment of cancer if it is recognized for treatment of that indication in a standard reference compendium or recommended in the medical literature even if the drug is not approved by the FDA for a particular indication.

Over-the-counter drugs

Eligible health services include certain over-the-counter medications, as determined by the plan. Coverage of the selected over-the-counter medications requires a **prescription**. You can access the list by logging on to your Aetna member website at www.aetna.com.

Prescription eye drop refills

Eligible health services include refills of **prescription** eye drops provided in accordance with guidance for early refills of topical ophthalmic products provided to Medicare Part D plan sponsors by the Centers for Medicare and Medicaid Services; and, if

- The **prescriber** indicates on the original **prescription** that additional quantities of the **prescription** eye drops are needed;
- The refill requested does not exceed the number of additional quantities indicated on the original **prescription** by the **prescriber**; and
- The **prescription** eye drops prescribed by the **prescriber** are a **covered benefit** under the plan.

Preventive care drugs and supplements

Eligible health services include preventive care drugs and supplements (including over-the-counter drugs and supplements) as required by the ACA guidelines when prescribed by a **prescriber** and the **prescription** is submitted to the pharmacist for processing.

Risk reducing breast cancer prescription drugs

Eligible health services include **prescription drugs** used to treat people who are at:

- Increased risk for breast cancer
- Low risk for adverse medication side effects

Tobacco cessation prescription and over-the-counter drugs

Eligible health services include FDA approved **prescription drugs** and over-the-counter (OTC) drugs to help stop the use of tobacco products, when prescribed by a **prescriber** and the **prescription** is submitted to the pharmacist for processing.

How you get an emergency prescription filled

You may not have access to a **network pharmacy** in an emergency or urgent care situation, or you may be traveling outside of the plan's **service area**. If you must fill a **prescription** in either situation, we will reimburse you as shown in the table below.

Type of pharmacy	Your cost share
Network pharmacy	• You pay the **copayment**.
Out-of-network pharmacy	• You pay the **pharmacy** directly for the cost of the **prescription**. Then you fill out and send a **prescription drug** refund form to us, including all itemized **pharmacy** receipts. • Coverage is limited to items obtained in connection with covered emergency and out-of-area urgent care services. • Submission of a claim doesn't guarantee payment. If your claim is approved, you will be reimbursed the cost of your **prescription** less your **network copayment/coinsurance**.

Where your schedule of benefits fits in

You are responsible for paying your part of the cost sharing. The schedule of benefits shows any benefit limitations and any out-of-pocket costs you are responsible for. Keep in mind that you are responsible for costs not covered under this plan.

Your **prescription drug** costs are based on:

- The type of **prescription** you use
- Where you fill your **prescription**

The plan may, in certain circumstances, make some **preferred brand-name prescription drugs** available to members at the generic **copayment** level.

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Biosimilar prescription drug

A biological **prescription drug** that is highly similar to a U.S. Food and Drug Administration (FDA) – licensed reference biological **prescription drug**, even though there may be minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the highly similar biological **prescription drug** and the reference biological **prescription drug** in terms of the safety, purity, and potency of the drug. As defined in accordance with FDA regulations.

Brand-name prescription drug

An FDA approved **prescription drug** marketed with a specific brand name by the company that manufactures it, usually by the company which develops and patents it.

Coinsurance

The specific percentage you have to pay for a health care service listed in the schedule of benefits.

Copay, **copayment**

The specific dollar amount you have to pay for a health care service listed in the schedule of benefits.

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Deductible

For plans that include a **deductible**, this is the amount you pay for **eligible health services** per year before your plan starts to pay as listed in the schedule of benefits.

Drug guide

A list of **prescription drugs** and devices established by **Aetna** or an affiliate. It does not include all **prescription drugs** and devices. This list can be reviewed and changed by **Aetna** or an affiliate. A copy of the **drug guide** is available at your request. Or you can find it on the **Aetna** website at www.aetna.com/formulary.

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Generic prescription drug, **generic drug**

A **prescription drug** with the same dosage, safety, strength, quality, performance and intended use as the brand name product. It is defined as therapeutically equivalent by the U.S. Food and Drug Administration (FDA) and is considered to be as effective as the brand name product.

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Mail order pharmacy

A **pharmacy** where **prescription drugs** are legally dispensed by mail or other carrier.

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Network pharmacy

A **retail**, **mail order** or **specialty pharmacy** that has contracted with **Aetna**, an affiliate or a third party vendor to provide outpatient **prescription drugs** to you.

Non-preferred drug

A **prescription drug** or device that may have a higher out-of-pocket cost than a **preferred drug**.

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Pharmacy

An establishment where **prescription drugs** are legally dispensed. This can be a **retail**, **mail order** or **specialty pharmacy.**

Preferred drug

A **prescription drug** or device that may have a lower out-of-pocket cost than a **non-preferred drug**.

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Retail pharmacy

A community **pharmacy** that dispenses outpatient **prescription drugs** at retail prices.

Specialty prescription drugs

These are **prescription drugs** that are prescribed to address a complex or chronic medical condition or a rare medical condition such as:

- Cancer
- Rheumatoid arthritis
- Hemophilia
- Multiple sclerosis
- Hepatitis C
- Cystic fibrosis
- Multiple myeloma

A complex or chronic medical condition means a physical, behavioral, or developmental condition that:

- May have no known cure
- Is progressive; or
- Can be debilitating or fatal if untreated or undertreated

A rare medical condition means a disease or condition that affects fewer than:

- 200,000 individuals in the United States; or
- Approximately 1 in 1,500 individuals worldwide

They will cost $ 600 or more for up to a 30-day supply and are not typically stocked at retail pharmacies. They also require a difficult or unusual process of delivery or require enhanced patient education, management, or support before or after use of the drug.

Specialty prescription drugs do not include a prescription drug prescribed to treat:

- Diabetes
- HIV or
- Aids

You can access the list of these **specialty prescription drugs**. See the *How to contact us for help* section for details.

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Specialty pharmacy

This is a **pharmacy** designated by **Aetna** as a network **pharmacy** to fill **prescriptions** for **specialty prescription drugs**.

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9. Outpatient prescription drugs

Plan features - maximums and limits

Important note: Copayments, if any, will never be more than the retail price of the prescription drug.

Waiver for risk reducing breast cancer prescription drugs
The **prescription drug** cost share will not apply to risk reducing breast cancer **prescription drugs** when obtained at a **network pharmacy**. This means they will be paid at 100%.

[Drafting note: For religious exempt ('RE') plans, do not include the Waiver for contraceptives content below when the form prints.]
[**Waiver for contraceptives**
The **prescription drug** cost share will not apply to female contraceptive methods when obtained at a **network pharmacy**. This means they will be paid at 100%. This includes certain OTC and generic contraceptive **prescription** drugs and devices for each of the methods identified by the FDA. If a therapeutically equivalent **generic prescription drug** is not available, the **brand-name prescription drug** for that method will be paid at 100%.

The **prescription drug** cost share will apply to **prescription drugs** that have a generic equivalent or biosimilar or generic alternative available within the same therapeutic drug class obtained at a **network pharmacy** unless you receive a medical exception. A therapeutically equivalent drug class is a group of drugs or medications that contain identical amounts of the same active drug ingredients in the same dosage form and route of administration and are used for the treatment of the same or similar disease or **injury.**]

Waiver for tobacco cessation prescription and over-the-counter drugs
The **prescription drug** cost share will not apply to treatment programs for tobacco cessation **prescription** and OTC drugs when obtained at a **retail network pharmacy**. This means they will be paid at 100%.

Per prescription cost share

Tier 1 -- preferred and non-preferred generic prescription drugs

Description	In-network coverage
For each 30 day supply filled at a **retail pharmacy**	$15 **copay,** no **deductible** applies
For all fills greater than a 30 day supply but no more than a 90 day supply filled at a retail or **mail order pharmacy**	$37.50 **copay,** no **deductible** applies

Tier 2 -- preferred brand-name prescription drugs

Description	In-network coverage
For each 30 day supply filled at a **retail pharmacy**	$65 **copay,** after **deductible**
For all fills greater than a 30 day supply but no more than a 90 day supply filled at a retail or **mail order pharmacy**	$162.50 **copay,** after **deductible**

Tier 3 -- non-preferred brand-name prescription drugs

Description	In-network coverage
For each 30 day supply filled at a **retail pharmacy**	$100 **copay,** after **deductible**
For all fills greater than a 30 day supply but no more than a 90 day supply filled at a retail or **mail order pharmacy**	$250.00 **copay ,** after **deductible**

Tier 4 -- preferred specialty prescription drugs (including biosimilar prescription drugs)

Description	In-network coverage
For each 30 day supply filled at a **retail pharmacy** or specialty **network pharmacy**	40% up to $150**,** after **deductible**
For fills greater than a 30 day supply but no more than a 90 day supply filled at a **retail pharmacy** or specialty **network pharmacy**	40% up to $375 (but no more than $150 per 30 day supply)**,** after **deductible**

Tier 5 - non-preferred specialty prescription drugs (including biosimilar prescription drugs)

Description	In-network coverage
For each 30 day supply filled at a **retail pharmacy** or specialty **network pharmacy**	50% up to $150**,** after **deductible**
For fills greater than a 30 day supply but no more than a 90 day supply filled at a **retail pharmacy** or specialty **network pharmacy**	50% up to $375 (but no more than $150 per 30 day supply)**,** after **deductible**

Diabetic supplies and insulin

Description	In-network coverage
For each 30 day supply filled at a **retail pharmacy**	Paid according to the tier of drug in the schedule of benefits, above
Diabetic test strips	0% no **deductible** applies

For all fills greater than a 30 day supply but no more than a 90 day supply filled at a **retail** pharmacy or **mail order pharmacy**	Paid according to the tier of drug in the schedule of benefits, above

Orally administered anti-cancer medications

Description	**In-network coverage**
For each 30-90 day supply filled at a **retail pharmacy** or specialty **network pharmacy**	$0 **copayment**

[Outpatient prescription contraceptive drugs and devices

Important note:

Prescription contraceptive drugs are covered up to a 12month supply.

Description	**In-network coverage**
Female contraceptives that are **generic** and OTC drugs and devices. For each 30 day but no more than 365 day supply	$0 per **prescription** or refill
Female contraceptives that are **brand-name prescription drugs** and devices. For each 30 day but no more than 365 day supply	Paid according to the tier of drug in the schedule of benefits, above if a therapeutically equivalent generic is available

Important note:

For in-network coverage, brand-name **prescription drugs** and devices covered at 100% to the extent that a therapeutically equivalent generic is not available.

Brand name contraceptives with a therapeutically equivalent generic will be paid according to the tier of drug in the schedule of benefits.]

Preventive care drugs and supplements

Description	In-network coverage
For each 30 day but no more than a 90 day supply filled at a **retail pharmacy** or **mail order pharmacy**	$0 per **prescription** or refill

Limitations: Coverage will be subject to any sex, age, medical condition, family history, and frequency guidelines in the recommendations of the United States Preventive Services Task Force. For details on the guidelines and the current list of covered preventive care drugs and supplements, see the *How to contact us for help* section.

Risk reducing breast cancer prescription drugs

Description	In-network coverage
For each 30 day but no more than a 90 day supply filled at a **retail pharmacy** or **mail order pharmacy**	$0 per **prescription** or refill

Limitations: Coverage will be subject to any sex, age, medical condition, family history, and frequency guidelines in the recommendations of the United States Preventive Services Task Force. For details on the guidelines and the current list of covered risk reducing breast cancer **prescription drugs**, see the *How to contact us for help* section.

Tobacco cessation prescription and over-the-counter drugs

Description	In-network coverage
For each 30 day but no more than a 90 day supply filled at a **retail pharmacy** or **mail order pharmacy**	$0 per **prescription** or refill

Limitations:

- Coverage only includes **generic drug** when there is also a brand-name drug available.
- Coverage is subject to any sex, age, medical condition, family history, and frequency guidelines in the recommendations of the United States Preventive Services Task Force. For details on the guidelines and the current list of covered tobacco cessation **prescription drugs** and OTC drugs, see the *How to contact us for help* section.

If you or your **prescriber** requests a covered **brand-name prescription drug** when a covered **generic prescription drug** equivalent is available, you will be responsible for the cost difference between the **generic prescription drug** and the **brand-name prescription drug**, plus the cost share that applies to **brand-name prescription drugs**.

Important note:

See the *Outpatient prescription drugs, Other services* section of the certificate of coverage for more information on other **prescription drug** coverage under this plan.

All formularies include generic drugs, which are in the lowest copay tier for members. Brand-name products may be considered preferred or non-preferred in the common three-tier plan design. Preferred brand-name drugs are encouraged with a lower copay than non-preferred brand-name products. Tiered benefit design encourages generic utilization and lower pharmacy cost through copay differentials. The goal is to include in the formulary the lowest net cost drug within each therapeutic class while ensuring that options available on the formularies are consistent with current standards of practice and clinical guidelines.

Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates factors that may affect the formulary. The FRC makes business recommendations based on such factors to the P&T Committee. It is important to note that any drug product must first be deemed safe and effective by the P&T Committee before it is considered eligible for inclusion on a CVS Caremark Formulary or Drug List, and that any recommendations made by the FRC must be approved by the P&T Committee before implementation.

The P&T Committee reviews all standard formularies annually. The review is conducted by drug class to assure that the formulary recommendations previously established are maintained and to recommend additional changes for clinical appropriateness if advisable based on newly available pharmaceutical information.

See the attached Policy and Procedure document for details of the CVS Caremark National Pharmacy and Therapeutics (P&T) Committee

Formulary benefit design and copay tiering are applied consistently across all drugs and drug classes and do not discriminate based on whether the drug is for a medical or surgical condition, mental health or substance use disorder diagnosis, or other health conditions. Any pharmacy coverage factors, sources or evidentiary standards, processes and development or implementation strategies applied to drugs used to treat mental health or substance use disorders are comparable to, and are applied no more stringently than the coverage factors, source or evidentiary standards, processes and development or implementation strategies used in applying the limitations to drugs used to treat medical or surgical

conditions. The formulary tiers are based on whether the drug is available as a generic or a brand product, and whether the brand or generic drug product is considered preferred or non-preferred.

Specialty Drug designation:

Specialty pharmacy member information indicates that members can get many commonly prescribed specialty medicines from a specialty pharmacy, or based on their plan, they can use a retail pharmacy. Specialty drugs treat complex, chronic conditions. A nurse or pharmacist will often support their use during treatment. These drugs may be injected, infused or taken by mouth. A member may need to refrigerate them. They are often expensive and may not be available at retail pharmacies. Contact information is provide for members to get access to specialty medications. Document is found at: https://www.aetna.com/docfind/cms/assets/pdf/specialty_pharmacy.pdf

Aetna delegates the Specialty Drug designation to CVS Caremark, except for the purpose of applying a copay or restricting distribution at a specialty pharmacy. The CVS Caremark specialty drug designation decision making process details include the specialty drug designation decisions made by CVS Caremark Pharmaceutical Technology Evaluation Committee (PTEC). The personnel involved in PTEC is multidisciplinary are voting members making decisions, and is comprised of internal employees' representatives from various business areas including Medical Affairs, Specialty Product Safety, Professional Practice and others. Details of the composition of PTEC personnel include pharmacists, physicians, and other businesspersons knowledgeable about the PBM business and pharmacy distribution channels. None of the personnel are MH/SUD specialists.
The PTEC committee meets quarterly to evaluate pharmaceuticals, biologics, medical devices and emerging technologies to determine specialty drug designation using an established decision model. CVS Specialty designation and removal decisions are made without regard to whether the drugs are used to treat MH/SUD conditions or MED/SURG conditions and is applied to drugs or drug classes using factors such as risk profile of a drug, safety and effectiveness of drug (e.g., close clinical monitoring), a drug's indication for use and cost, a drug's route of administration or delivery systems, a drug's dispensing requirements (i.e., special handling, special storage). Due to the special handling of the drug or the drug's limited distribution imposed by a manufacturer, the prescription may or may not need to be dispensed from a Specialty Pharmacy.

Items i-viii are not considered NQTLs. The elements "Therapeutic substitution, Generic substitution, Exclusions/non-formulary, Denials, Limited distribution, Preventive Medications, Therapeutic duplications Restrictions", when applicable, they are part of the factors defined and explained in Step 2 for each of the NQTLs Formulary Design and Tiering and Specialty Drug Designation.

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How can I request a medical exception?

Sometimes you, someone who represents you or your **provider** may ask for a medical exception for drugs that are not covered. You, someone who represents you or your **prescriber** can contact us. You will need to provide us with the required clinical

documentation.. We will make a coverage determination within 72 hours after we receive your request and any information that supports it and will tell you, someone who represents you and your **provider** of our decision. Any exception granted is based upon individual circumstances and is a case by case decision. For directions on how you can submit a request for a review:

- Contact member services using the number on the back of your **Aetna** ID card
- Go online at [aetna.com]

If you are denied a medical exception based on the above processes, you may request review by an independent external review organization. We will tell you, someone who represents you or your **provider** of the external review determination no later than 72 hours after we receive your request. For quicker medical exceptions in urgent situations, we will tell you, someone who represents you or your **provider** of the external review determination no later than 24 hours after we receive your request.

Per the language provided above, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide; members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received. Coverage requests data for 2021 matched by drug GPI to the drug list was reviewed. Quality control of the data by a PBM pharmacist found that not all requests processed did not match GPI. These non-matching GPIs were also reviewed and are here reported, and are considered to be in-scope since they did not match due to the drug not being present in the drug list. A second PBM pharmacist inspected the data for accuracy. Findings:

		Totals	Totals
		Med/Surg	MH/SUD
1	Number of requests pursuant to § 15-831(c)(1) for coverage of a drug that is not on the formulary	0	0
a	Number of requests in line 1 that were denied as adverse decisions	0	0
b	Number of requests in line 1 that were approved	0	0

- MH/SUD drugs being denied Exchange Formulary list is empty

Examination of the same 2021 requests for coverage data by a PBM pharmacist (both matched GPI and non-matched), revealed that no prescription request had been denied due to experimental/investigational determinations.

B. Identify the factors used in the development of the limitation(s);

For both Formulary Tiering and Design and Specialty Drug designation NQTLs, no factors were considered and then rejected. A factor may not be applicable for a particular drug (for example there may be no pipeline information, or there may not be a regulatory requirement affecting the drug) and, in such instance it may not be used, but the factors are not rejected.

For both Formulary Tiering and Design and Specialty Drug designation NQTLs, no factor was given more weight than another.

The same factors are considered when establishing formulary tier designation for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions, all factors are considered.

The factors used are:

Factors	Sources
Brand or generic status of the drug	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com
Impact of generic drugs or drugs designated to become available over-the-counter	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm
Brand and generic pipeline	CVS Caremark pipeline reports based on manufacturer information, or manufacturer pipeline information For example: CVS Health Payor Solutions. Drugs to Watch. Drug Pipeline https://payorsolutions.cvshealth.com/tags/drug-pipeline

	Bristol Myers Squibb Pipeline website https://www.bms.com/researchers-and-partners/in-the-pipeline.html Note: there are thousands of manufacturers, these are just examples.
Line of business	Per regulatory requirement state or federal as applicable
Availability of therapeutic alternatives	Advanced Control Formulary and Standard Opt Out Formulary. Formulary, or drug list drugs used for the disease or condition in question.
Indication for use and cost (cost-effectiveness)	Utilization trends reports Plan sponsor cost reports Applicable manufacturer agreement
Potential impact on members	Advance Control Formulary and Standard Opt Out Formulary. Formulary, or drug list drugs used for the disease or condition in question.

Specialty Drug designation:

The same factors are considered when applying specialty drug designation for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

Factors	**Sources**
Risk profile	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples:

	Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 6, 2023. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/
Safety and effectiveness	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples: Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 6, 2023. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/
Indication for use and cost	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Cost information from internal database

Route of administration or delivery systems	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples: Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 6, 2023. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/
Dispensing requirements	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples: Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 6, 2023.

	Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

The same factors and standards are considered when establishing formulary tier and design for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

Factors	Definitions	Sources	Standard
Brand or generic status of the drug	The FDA definition of a brand drug, and a generic drug.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	FDA definition of a brand drug, and a generic drug.

Impact of generic drugs or drugs designated to become available over-the-counter	The FDA definition of a brand drug, and a generic drug.	1. Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm 2. Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com 3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm	FDA definition of a over-the-counter drug, and/or a generic drug.
Brand and generic pipeline	Drugs that are in late stage development as defined by the pharmaceutical industry	CVS Caremark pipeline reports based on manufacturer information, or manufacturer pipeline information.	As communicated by drug manufacturers

		For Example: CVS Health Payor Solutions. Drugs to Watch. Drug Pipeline https://payorsolutions.cvshealth.com/tags/drug-pipeline Examples of manufacturer's pipeline: https://www.abbvie.com/science/pipeline.html https://www.regeneron.com/pipeline-medicines Note: there are thousands of manufacturers, these are examples	
Line of business	Category of insurance, such as Commercial, Medicare, Health Insurance Marketplace, etc.	Per regulatory requirement state or federal as applicable	Per regulatory requirement state or federal as applicable
Availability of therapeutic alternatives	Alternative drugs available to treat the same condition.	1. Other drugs used for the same disease or condition already in the formularies Advanced Control Formulary and Standard Opt Out. 2. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example: https://www.guidelinecentral.com/guidelines/	Disease/ condition-dependent
Indication for use and cost (cost-effectiveness)	This factor is not considered by the P&T Committee. Cost effectiveness is when multiple drugs exist to treat a given condition,	Utilization trends reports Plan sponsor cost reports Applicable manufacturer agreement	There is no set threshold, since this is a qualitative comparison. Drug dependent qualitative measure:

	the drugs that are less costly provide more cost-effective therapy. The plan sponsor cost is the net cost option for generic, biosimilar, and brand-name drugs being considered.		The cost is a relative measure looking at price of a drug measured in comparison to the price of another drug or group of drugs that are used for the same indication. A cost can be higher than, similar to, or lower than other drugs that are used for the same indication
Potential impact on members	If the decision to remove of a drug will impact patients negatively because there are no comparable therapeutic alternatives left in the formulary to treat the disease or condition.	Advance Control Formulary and Standard Opt Out Formulary. Formulary, or drug list drugs used for the disease or condition in question.	Drug-dependent qualitative measure: Large impact occurs when the formulary in question does not have enough drugs choices to treat the disease or condition. Low impact occurs when the formulary in question has multiple drugs choices to treat the disease or condition.

Specialty Drug designation:

The same factors and standards are considered when establishing specialty designation for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

Factors	Definitions	Sources	Standards
Risk profile	The risk characteristics associated with the drug such as box warnings, REMS, adverse drug reactions and patient monitoring requirements.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm	As assigned by the FDA. For further information, please see: 1. FDA's Application of Statutory Factors in Determining When a REMS is Necessary: Guidance for Industry. 2. Black box" 101: How the Food and Drug Administration evaluates, communicates, and manages drug

		Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	benefit/risk https://www.jacionline.org/article/S0091-6749(05)02325-0/fulltext
Safety and effectiveness	The level of patient proficiency needed for self-management and maintaining adherence, as well as any required therapeutic response monitoring and dose adjustments.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.	As assigned by the FDA and described in the FDA labeling. For further information, please see: FDA's Labeling Resources for Human Prescription Drugs. https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs

		https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	
Indication for use and cost	The indication is what the drug is used for. The cost is a relative price measured in comparison to other drugs for the same indication. The complexity of the condition where the drug is intended for use (e.g., rare, chronic) and its actual or anticipated cost.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Cost information internal database.	There is no set threshold, since this is a qualitative comparison. The indication is as assigned in the drug labeling by the FDA. The cost is a relative measure looking at price of a drug measured in comparison to the price of another drug or group of drugs that are used for the same indication. A cost can be higher than, similar to, or lower than other drugs that are used for the same indication.
Route of administration or delivery systems	The level of complexity to administer the drug, such as via infusion, injection or inhalation and whether the administration of the drug requires ancillary supplies and/or a device.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm	A route is required by the FDA labeling. Standard routes of administration are known by clinicians making decisions to be easier or more difficult to execute by a patient or may require administration by a health care provider.

		Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	
Dispensing requirements	The storage and handling requirements for the drug and any necessary coordination of care with a provider.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.	A storage and handling requirements are required by the FDA labeling and as required by the manufacturer. This is a qualitative measure known to clinicians and communicated by drug manufacturers. For example, the handling and storage of a complex drug that is susceptible to thermal stress, and its transport and delivery must be coordinated with the health care provider to avoid spoilage.

		https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	

D. Identify the methods and analysis used in the development of the limitation(s); and

Comparative analyses demonstrating comparability and no more stringency in application of factors as written was performed by PBM Clinicians via a review of the policies and procedures detailing the PBM formulary management, P&T Committee process, and sample of committee minutes. The policies and procedures and the minutes as written used do not show a different process for MH/SUD drugs from M/S drugs, and no separate policies as procedures exist for MH/SUD drugs. The meeting minutes reveal that no separate meetings occur to vote on decision about MH/SUD drugs. All drugs are voted on using the same process for MH/SUD and M/S drugs. Factors and sources used were not explicit in all policies and procedures and minutes reviewed, however no deviations from factors used were noted in the minute meetings or policies and procedures, and examples of decisions did not show evidence that more restrictive decisions are being made.

Formulary Review Committee (FRC) is an internal CVS Caremark committee that makes business recommendations to the P&T Committee, as written in the formulary management policy based on factors utilization trends and/or drug spend, client cost, applicable manufacturer agreements, impact of generic drugs and drugs designated to become OTC, brand and generic pipeline, client mix (line of business), plan member disruption. Any drug product must first be deemed safe and effective by the P&T Committee before it is considered eligible for inclusion on a CVS Caremark Formulary, and that any recommendations made by the FRC must be approved by the P&T Committee before implementation. The National P&T Committee reviews and approves all inclusions or exclusions to the formulary. The FRC meets a minimum of 10 times per year and on an ad hoc basis to meet emergent business needs. The FRC meeting agenda is set in advance based on previous open action items and/or requests received since the prior meeting and are electronically distributed to the committee members. Recommendations for additions and deletions are voted on by FRC and then forwarded to the National P&T Committee for final review and approval. All CVS Caremark formularies are submitted to and approved by the National P&T Committee. The P&T Committee reviews all standard formularies annually. The FRC votes on bringing forth business formulary recommendations to the P&T Committee.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

This internal review determined that the Committee members were comprised of comparable experts for MH/SUD conditions and medical/surgical conditions, and that such experts evaluated and applied the factors in a comparable manner for tiering, specialty designation.

The meeting minutes reveal that no separate meetings occur to vote on decision about MH/SUD drugs vs. M/S drugs. Examination of the past two years FRC Meeting minutes revealed that no different committee members were used in decisions for MH/SUD drugs from M/S drugs, and factors used brand/generic status, pipeline new to market information, line of business (commercial, Medicare part D, etc.), information found in FDA approved drug labeling (drug class, category, brand name, dosage form, etc.) are explicit in the minutes, and are not different for MH/SUD drugs than for M/S drugs. The factors availability of therapeutic alternatives and cost effectiveness and potential impact on members, are not explicit in the FRC minutes. Nevertheless, decisions about MH/SUD drugs do not have a different process from M/S drugs or reached more restrictive decisions. For example, on minutes dated 01/06/2022 an FRC decision was made to bring forth a business formulary recommendation to P&T Committee about adding new SUD naloxone spray generic launch to tier 1 for ACF and SOO formularies, the same decision was made for the M/S drug adapalene-benzoyl peroxide gel due to a generic launch. Additionally, on minutes dated 04/06/2022 an FRC decision was made to bring forth a business formulary recommendation to P&T Committee about adding new MH drug LOREEV XR cap to tier 3, and the same decision was made for new M/S drug orphenadrine, aspirin, and caffeine combination tab to tier 3.

Factors	**SUD Drug** **Sources for** naloxone spray generic launch add to Tier 1	**M/S Drug** **Sources for** adapalene-benzoyl peroxide gel launch **add to Tier 1**
Brand or generic status of the drug	DailyMed - NALOXONE HYDROCHLORIDE- naloxone hydrochloride nasal spray inhalant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=68723486-8f21-4299-b380-7d5e3f9657b6	DailyMed - ADAPALENE AND BENZOYL PEROXIDE gel (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=05babd5f-18ab-4646-8962-cb000ed0f9a8
Impact of generic drugs or drugs designated to become available over-the-counter	DailyMed - NALOXONE HYDROCHLORIDE- naloxone hydrochloride nasal spray inhalant (nih.gov)https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=68723486-8f21-4299-b380-7d5e3f9657b6	DailyMed - ADAPALENE AND BENZOYL PEROXIDE gel (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=05babd5f-18ab-4646-8962-cb000ed0f9a8

	1. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm Note this drug was not OTC in 2021.	1. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm Note this drug was not OTC in 2021.
Brand and generic pipeline	Pipeline website generic launch announced: https://www.us.sandoz.com/news/media-releases/sandoz-launches-authorized-generic-narcan-naloxone-hydrochloride-nasal-spray-4	Pipeline website generic launch announced: https://www.businesswire.com/news/home/20211201005573/en/
Line of business	Commercial	Commercial
Availability of therapeutic alternatives	Available therapeutic drugs information is found at: Substance Abuse and Mental Health Services Administration – SAMHSA – Opioid Overdose https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/opioid-overdose	Available therapeutic drugs information is found at: Journal of the American Academy of Dermatology - Guidelines of care for the management of acne vulgaris https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext
Indication for use and cost (cost-effectiveness)	Generic relative cost is lower than brand	Generic relative cost is lower than brand
Potential impact on members	This is a new drug. The decision was to add to formulary preferred, the impact is not negative since this offers another therapeutic option to many existing ones.	This is a new drug. The decision was to add to formulary as preferred, the impact is not negative since this offers another therapeutic option to many existing ones.

The meeting minutes reveal that no separate meetings occur to vote on decision about MH/SUD drugs vs. M/S drugs. Examination of the past two years P&T Committee minutes revealed no different committee members were used in decisions for MH/SUD drugs from M/S drugs, and factors used brand/generic status, pipeline new to market information, line of business (commercial, Medicare part D, etc.), information found in FDA approved drug labeling (drug class, category, brand name, dosage form, etc.) are explicit in the minutes, and are not different for MH/SUD drugs than for M/S drugs. For example, in P&T Committee minutes dated 6/2/2021 a decision was made to add MH drug Qelbree (viloxazine ER) oral capsules to the formularies with a non-preferred status. There was a note about the rationale for a decision about this drug stating the generic

atomoxetine and/or guanfacine ER. On the same minutes, a decision was made to add the M/S drug Zegalogue (dasiglucagon) SC injection at the non-preferred Brand Specialty tier. The minutes indicate that the same clinical pharmacist with a Pharm D provided an overview of the drugs to the committee including FDA Approved indications, efficacy and safety information, clinical trials and clinical rationale in supporting materials. Comments about the MH drug was made by an MD Psychiatry Specialist and a MD Pediatrics Specialist; a comparable MD -PhD in Endocrinology Specialist provided comments about the M/S drug. The factors considered were that both these drugs are brand and do not have a generic or OTC version available, there is no pipeline information available from the manufacturers, the line of business is the same (commercial) for both drugs, clinical comments from the comparable credentialled physicians considered alternative therapies in the a comparable manner, and not comment was more stringent because a drug was used for mental health, cost related factors were not considered by P&T Committee and the impact on members was similar, since the decision was the same, to add to a non-preferred tier.

The sources of information are not explicit in the minutes but the PBM clinician analyzing the decision can find the following information consistent with the sources and standards as described in the process:

Factors	**Sources for Qelbree (viloxazine ER) Mental Health Drug**	**Sources for Zegalogue (dasiglucagon) SC injection Medical/Surgical Drug**
Brand or generic status of the drug	DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a	DailyMed - ZEGALOGUE- dasiglucagon injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=14704879-872c-4967-8779-04a3bbdfb4e6
Impact of generic drugs or drugs designated to become available over-the-counter	2. DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a 3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm	2. DailyMed - ZEGALOGUE- dasiglucagon injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=14704879-872c-4967-8779-04a3bbdfb4e6 3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm
Brand and generic pipeline	Pipeline website: https://www.supernus.com/research-development	Pipeline website:

		https://www.novonordisk.com/science-and-technology/r-d-pipeline.html
Line of business	Commercial	Commercial
Availability of therapeutic alternatives	The comment in minutes considered the availability of other brand and generics and advantages of other formulary to add the comment about agents in comparison, and that this drug would generally be a third-line or fourth line use given the availability of numerous alternatives.	The comment in minutes considered the availability of other brand and generics stating that this drug is a positive ready-to-use product rather than products that must be reconstituted, and having the benefit of long shelf live, and patients needed less frequent refills advantages.
Indication for use and cost (cost-effectiveness)	This factor is not considered by the P&T Committee.	This factor is not considered by the P&T Committee.
Potential impact on members	This is a new drug. The decision was to add to formulary as non-preferred, the impact is not negative since this offers another therapeutic option to many existing ones.	This is a new drug. The decision was to add to formulary as non-preferred, the impact is not negative since this offers another therapeutic option to many existing ones.

According to their policy, the National Pharmacy and Therapeutics Committee (P&T Committee) is an independent group of clinical experts that objectively appraises and evaluates drugs to be considered for the CVS Caremark National Formulary and the CVS Caremark formularies. According to the Formulary Development and Management at CVS Caremark white paper, the voting members on the P&T committee are not employees of CVS Caremark. According to the P&T Committee policy, the P&T Committee meets on a regular basis and not less frequently than on a quarterly basis; if an emergent issue exists that needs to be reviewed between regularly scheduled meetings, an ad hoc meeting may be convened or an email vote taken; all P&T Committee decisions are documented in writing; excluded from attendance are any product sponsor representative. The P&T Committee votes on adopting formulary recommendations.

Specialty Designation: Comparative analyses demonstrating comparability and no more stringency in application of factors as written was performed by PBM Clinicians via a review of written materials, power point presentation about the PTEC process, past two years committee minutes.

This internal review determined that the Committee members were comprised of comparable experts for MH/SUD conditions and medical/surgical conditions, and that such experts evaluated and applied the factors in a comparable manner for specialty designation. The written materials and the minutes as written used do not show a different process for MH/SUD drugs from M/S drugs, and no separate policies as procedures exist for MH/SUD drugs.

The meeting minutes reveal that no separate meetings occur to vote on decision about MH/SUD drugs vs. M/S drugs. All drugs are voted on using the same process for MH/SUD and M/S drugs. Factors and sources used were not explicit in all policies and procedures and minutes reviewed, however there are no deviations from factors used noted in the minute meetings or written material. Examples of decisions did not show evidence that more restrictive decisions are being made. PBM clinician doing the analysis can find the drug-specific sources by searching the same databases indicated as sources.

Examples of decisions made by PTEC include, per Q2-2021 minutes, the designation of the MH drug Zyprexa Relprevv (olanzapine) as not specialty. The factors used were: the risk profile having serious adverse effects if not used properly; the safety and effectiveness drug information source showing a high risk of complications with nonadherence and monitoring required; the restricted distribution based upon REMS and box warning; the dispensing requirements present for mail and retail to not dispense if pharmacy is unable to meet REMS requirements; indication for use the maintenance treatment of schizophrenia in adults. This decision was compared to the decision made by PTEC per Q2-2021 minutes about the designation of the M/S drug Ozurdex (dexamethasone intravitreal implant) as specialty. The factors used were risk profile as the drug having the risk of post-operative complications; safety and effectiveness of the drug having high risk of complications needing coordination of care; distribution deemed as limited; dispensing requirements needing coordination of care; indication for use as non-infectious uveitis affecting the posterior segment of the eye and for diabetic macular edema.

The sources of information are not explicit in the minutes but the PBM clinician analyzing the decision can find the following information consistent with the sources and standards as described in the process:

Factors	**Sources for Zyprexa Relprevv**	**Sources for Ozurdex**
Risk profile	1. DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241 2. Zyprexa Relprevv (fda.gov) https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems	1. DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f 2. No REMS found searching the Approved Risk Evaluation and Mitigation Strategies (REMS) (fda.gov) https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
Safety and effectiveness	Zyprexa Relprevv - olanzapine pamoate kit medication guide https://pi.lilly.com/us/zyprexa_relprevv_medguide.pdf	See patient education found at OZURDEX® Resources for Your Practice | OZURDEX® for HCPs https://hcp.ozurdex.com/resources

Indication for use and cost	1. DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241 2. Cost is found in internal database to be greater than olanzapine generic tablets and to other drugs for schizophrenia.	1. DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f 2. Cost is found in internal database to be greater than dexamethasone generic ophthalmic and to other drugs for ocular inflammation.
Route of administration or delivery systems	DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241	DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f
Dispensing requirements	DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241	DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f

Methodology used for in operations analysis Formulary Tiering and Design:

A PBM analyst using a drug coverage extract followed these steps:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drugs were organized into formulary tier groups.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration.
- Counts of drugs and percentages on each formulary tier were summarized.
- Percentages of drugs with preferred status were summarized.

Qualitative assessment was done to identify if less percent of MH/SUD drugs were available overall in preferred tiers (not by tier). Only if such result was present, further analysis was done of how the decisions were made, aiming to identify any possible more stringent use of the factors in the decision-making process.

Quality assurance was performed by another PBM clinician looking at formulary data after the analysis tables were generated, and spot checking the tables to make sure the counting of drugs was done accurately and correlate with the original drug coverage extract.

Methodology used for in operations analysis Specialty Drug designation:

A PBM analyst using a drug coverage extract followed these steps:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drugs were organized into formulary tier groups.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts of drugs with Specialty drug designation and percentages with Specialty drug designation compared to total drug count on each formulary tier were summarized.
- Percentage of drugs with Specialty drug designation in the category was summarized.

Qualitative assessment was done to identify if more percent of MH/SUD drugs were designated overall as Specialty (not by tier). Only if such result was present, further analysis was done of how the decisions were made, aiming to identify any possible more stringent use of the factors in the decision-making process.

Quality assurance was performed by another PBM clinician looking at formulary data after the analysis tables were generated, and spot checking the tables to make sure the counting of drugs was done accurately and correlate with the original drug coverage extract.

MD-Instructions for MHPAEA NQTL Analysis Report and Data Report (8-6-21).pdf (adobe.com)

Methodology used for in operations analysis non-covered in formulary drug;

Methodology data for 2021 requests matched by drug GPI to the drug list was reviewed. Quality control of the data by a PBM pharmacist found that prior authorizations processed did not match GPI for every record due to the drug not being present in the drug list. These non-matching GPIs were also reviewed and are here reported.

There are no MH/SUD drugs being denied.

Formulary Tiering and Design and Specialty Drug designation:

FORMULARY TIERING FOR: Aetna Maryland Small Group Exchange 2021 Formulary - Pharmacy Benefit plan

- Tier 0 = ACA Preventive Drugs
- Tier 1 = Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands
- Tier 4 = Preferred Specialty
- Tier 5 = Non-Preferred Specialty

FORMULARY TIERING ANALYSIS	
Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021	
Category	**Analysis**

Medical / Surgical	Medical / Surgical	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	72	985	137	157	199	196	1,746	79.8%
	% of Drug Count per Tier	4.1%	56.4%	7.8%	9.0%	11.4%	11.2%		
Mental Health	**Mental Health**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**	**% Preferred****
	Drug Count by Tier	0	115	2	12	0	3	132	88.6%
	% of Drug Count per Tier	0.0%	87.1%	1.5%	9.1%	0.0%	2.3%		
Substance Use Disorder	**Substance Use Disorder**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**	**% Preferred****
	Drug Count by Tier	4	6	1	0	2	0	13	100.0%
	% of Drug Count per Tier	30.8%	46.2%	7.7%	0.0%	15.4%	0.0%		

* Note: Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
** Preferred Tier includes: Tier 0 = ACA Preventive Drugs, Tier 1 = Generics, Tier 2 = Preferred Brands and Tier 4 = Preferred Specialty

Comparative Analysis for formulary tier designation Aetna Maryland Small Group Exchange 2021 Formulary - Pharmacy Benefit plan

When the factors for formulary tier designation are considered consistently across all drugs and drug classes, the outcome shows that there is a higher percentage of drugs covered at preferred formulary tiers in the MH and SUD drug categories compared to the MED/SURG drug categories.

- The Medical/Surgical category has 79.8% of the drugs at a preferred formulary tier.
- The Mental Health category has 88.6% of the drugs at a preferred formulary tier.
- The Substance Use Disorder category has 100.0% of the drugs at a preferred formulary tier.

Specialty Drug designation: Aetna Maryland Small Group Exchange 2021 Formulary - Pharmacy Benefit plan

SPECIALTY DRUG CLASSIFICATION ANALYSIS									
Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021									
Category		Analysis							
Medical / Surgical	Medical / Surgical	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	0	45	34	5	191	194	469	26.9%
	% of Specialty Drugs per Tier	0.0%	9.6%	7.2%	1.1%	40.7%	41.4%		
	Mental Health	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty

Mental Health	**Specialty Drug Count by Tier**	0	0	0	0	0	3	3	**2.3%**
	% of Specialty Drugs per Tier	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%		
Substance Use Disorder	**Substance Use Disorder**	**Tier 0**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Specialty Drugs**	**% Specialty**
	Specialty Drug Count by Tier	0	0	0	0	2	0	2	**15.4%**
	% of Specialty Drugs per Tier	0.0%	0.0%	0.0%	0.0%	100.0%	0.0%		

* Note: Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration

Comparative Analysis for Specialty drug designation Aetna Maryland Small Group Exchange 2021 Formulary - Pharmacy Benefit plan

When the factors for Specialty drug designation are considered consistently across all drugs and drug classes, the outcome shows that the MH and SUD drug categories have a lower percentage of drugs designated as a Specialty drug compared to the MED/SURG drug category.

- The Medical/Surgical category has 26.9% of the drugs with a Specialty drug designation.
  - The drugs in the MED/SURG drug category with Specialty drug designation on Tier 1, Tier 2, and Tier 3 antiretroviral drugs used to treat HIV and immunosuppressive agents used with transplants, which are placed on non-specialty formulary tiers.
- The Mental Health category has 2.3% of the drugs with a Specialty drug designation.
  - The 3 drugs in the MH drug category with a Specialty drug designation include: Nuplazid caps/tabs; and Hetlioz caps.
- The Substance Use Disorder category has 15.4% of the drugs with a Specialty drug designation.
  - The 2 drugs in the SUD drug category with a Specialty drug designation include: Sublocade and Vivitrol inj.

Further Comparative Analysis for formulary tier designation and Specialty drug designation The 3 MH drugs placed in the non-preferred Tier 5 are the antipsychotics Nuplazid tablets and capsules, and the hypnotic Hetlioz capsule. PBM clinicians further analyzed the factors used to place these drugs in the non-preferred tier. Findings: all 3 drugs are brands[1,2] , none where designated to become available over-the-counter[3], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[4], the line of business (commercial) did not require that these drugs be placed in a particular tier[5], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2], therapeutic alternative drugs were plentiful and available in lower tiers already[6]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[7]. We looked at the following sources to inform each factor:

1. DailyMed - NUPLAZID- pimavanserin tartrate capsule NUPLAZID- pimavanserin tartrate tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e6bea44-57d6-4bac-9328-46e1ee59f83b
2. DailyMed - HETLIOZ- tasimelteon capsule HETLIOZ LQ- tasimelteon suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90
3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm

4. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com)
5. Per regulatory requirement state or federal as applicable.
6. Exchange Formulary – 2021 Tier 1, antipsychotics and hypnotic alternatives consistent with clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors.
    a. American Psychological Association (APA) Treatment of Patients with Schizophrenia. https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841
    b. American Academy of Sleep Medicine – Pharmacologic Treatment of Chronic Insomnia in Adults. https://jcsm.aasm.org/doi/10.5664/jcsm.6470

7. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file.

PBM clinicians further analyzed the factors used to place some example drugs of the 199 (191) M/S medications in Tier 4, to ascertain that the MH drugs placed in the non-preferred Tier 5 are not being placed more stringently (there are 8 non-specialty drugs in the specialty tier). Examples are: Ibrance[1], Kisqali[2] and Sprycel[3]. Findings: all 4 drugs are brands[1,2,3], none where designated to become available over-the-counter[4], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[5], the line of business (commercial) did not require that these drugs be placed in a particular tier[6], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1-3], therapeutic alternative drugs were NOT plentiful and available in lower tiers warranting that they NOT be placed int the highest formulary tier available[7]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[8]. We looked at the following sources to inform each factor:

1. DailyMed - Search Results for ibrance (nih.gov) https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=ibrance&pagesize=200&page=1
2. DailyMed - KISQALI- ribociclib tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aaeaef94-f3f5-4367-8ea2-b181d7be2da8
3. DailyMed - SPRYCEL- dasatinib tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4764f37b-c9e6-4ede-bcc2-8a03b7c521df
4. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm
5. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com)
6. Per regulatory requirements state or federal as applicable.
7. Exchange Formulary – 2021 Tier zero or 1 antidepressants, antipsychotics and hypnotic alternatives consistent with guideline examples found:

    Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example:

a. https://www.guidelinecentral.com/guidelines/
b. National Comprehensive Cancer Network https://www.nccn.org/guidelines/category_1

8. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file

Note: Aetna delegates the Specialty Drug designation to CVS Caremark, except for the purpose of applying a copay or restricting distribution at a specialty pharmacy.

Tiering Designation There are drugs that are not designated specialty that are in specialty Tier 4 and 5 and counted in the Formulary Tiering Analysis Table
Methodology looked at the overall drugs placed on more accessible preferred positions and did not find a more stringent overall treatment for MH and SUD. Tier zero is a regulatory mandate by ACA for Exchange Plans at $0 copay for members. Tier 1 is the next lowest copay tier providing the most access to members.

- Tier zero and Tier 1 has 87.1 % of the MH drugs and 30.8% + 46.2% = 77.0% of the SUD drugs.

Specialty Designation **Please explain the statement: "The drugs in the MED/SURG drug category with Specialty drug designation on Tier 1, Tier 2, and Tier 3 [are] antiretroviral drugs used to treat HIV and immunosuppressive agents used with transplants, which are placed on non-specialty formulary tiers."**

a. Are the drugs considered non-Specialty? No, as previously stated some HIV and immunosuppressive drugs have Specialty drug designation from the CVS Caremark PTEC Committee. CVS Clients in Maryland, such as Aetna, ensure that they are not treated as specialty for the purpose of charging a copay or restricting their availability to specialty pharmacies, by placing them in non-specialty tiers. Aetna delegates the Specialty Drug designation to CVS Caremark, except for the purpose of applying a copay or restricting distribution at a specialty pharmacy.

b. Where are these drugs counted in the non-Specialty Tiering Designation Table? There is no "non-Specialty Tiering Designation Table" in our submission. These drugs are counted on both the FORMULARY TIERING ANALYSIS table and the SPECIALTY DRUG CLASSIFICATION ANALYSIS table.

c. Does the key for the 5 tiers for Non-Specialty Tiering Designation Table also apply here? No. The key only applies to the FORMULARY TIERING ANALYSIS table

Findings and Conclusion of Formulary Tiering and Design: The basis for the conclusion that both as written and in operation, the processes, evidentiary standards, and factors used to impose the Formulary Tier Designation NQTL on MH/SUD drugs are comparable to and applied no more stringently than the processes, evidentiary standards, and factors used to impose the NQTL on M/S drugs, is the analysis findings as follows. As written the analyzed decisions about MH/SUD drugs do not have a different process from M/S drugs or reached more restrictive decisions. Based on minutes FRC decision was made to bring forth a business formulary recommendation to P&T Committee about adding new generic

launch for SUD drug tier 1 for ACF and SOO formularies, the same decision was made for the M/S generic launch. Additionally, on minutes FRC decision was made to bring forth a business formulary recommendation to P&T Committee about adding new MH brand drug to tier 3, and the same decision was made for new M/S brand drug to tier 3. Also, the analysis of the factors and the level of evidence for the sources used to inform the factors, as written in the policies show a consistent application process arrives at the same decision. The sources of information are not explicit in the minutes but the PBM clinician analyzing the decision can find the sources and standards as described in the process and assess that the process was followed consistently. Similarly, decisions made by P&T Committee about new brand drugs were consistent, adding these new brand drugs as non-preferred when there was evidence of multiple alternative options already available in the formulary; also, the clinical comments made by physicians of comparable credentials for MH/SUD as compared to M/S drugs were evident. Although the sources were not explicit in the P&T minutes, PBM clinicians can find the sources and assess that they were used no more restrictively to make decisions about MH/SUD as compared to M/S drugs. The sources are different for each drug because the information must be drug specific. In operations the overall results and comparison showing greater percentage of drugs are preferred in each MH, SUD and M/S. Note: more drugs in preferred tiers means more options for the enrollees:

Advanced Control Formulary 2021 Plan – Aetna preferred tier

- The Medical/Surgical category has 58.6%
- The Mental Health category has 74.6%
- The Substance Use Disorder category has 57.9%

Standard Opt-Out Formulary 2021 Plan – Aetna preferred tier

- The Medical/Surgical category has 66.6% of the drugs at a preferred formulary tier.
- The Mental Health category has 78.4% of the drugs at a preferred formulary tier.
- The Substance Use Disorder category has 66.7% of the drugs at a preferred formulary tier.

Also, the analysis of the factors and the level of evidence used for the sources used to inform the factors, in operations show a consistent process. No unique process exists that is different in any way to apply the factors; sources used are different and drug/disease-specific.

- ACF Tier 2: Only 5.3% of SUD and 5.8% of MH medications versus 8.7% of M/S medications while Tier 1: 47.4% SUD and 68.8% of MH medications versus 40.7% of M/S medications
- ACF Tier 4: Of the medications considered Specialty (in Tiers 4 and 5), none of the 6 MH medications was preferred compared to 53.8% of the 407 M/S medications considered Specialty
- SOO Tier 2: Only 5.6% of SUD and 8.8% of MH medications versus 10.9% of M/S medications while Tier 1: 55.6% SUD and 69.6% of MH medications versus 47.1% of M/S medications.
- SOO Tier 4: Of the medications considered Specialty (in Tiers 4 and 5), none of the 6 MH medications was preferred compared to 53% of the 400 M/S medications considered Specialty

Further analysis as requested by MIA was added in Step 5 and did not reveal that the process is followed more stringently. The reason for the difference is that not as many available therapeutic alternative drugs exist in lower tiers for those diseases, warranting that they NOT be placed int the highest formulary tier available. The process, and evidentiary standards used to apply formulary design and tiering to mental health or substance use disorder are the same, and are applied no more stringently than the specialty drug designation decided for drugs used to treat medical or surgical disorders both as written and in operations. This analysis was done by PBM Clinicians, they are pharmacists, and they made no recommendations regarding NQTLs applied to MH/SUD and M/S drugs. No variation in the use of PBM Clinicians for MH/SUD compared to M/S NQTL analyses.

Findings and Conclusion for non-formulary coverage requests: PBM pharmacists looking at the data for coverage requests for drugs not covered in the formulary found that for ACF the number of MH/SUD totaling 10 requests for coverage is too small to draw conclusions of non-parity. However, a deeper dive into what types of drugs where denied (only 3 drugs) showed that the drugs all have therapeutic alternatives available in the formulary. For SOO no MH/SUD drugs had requests received.

Findings and Conclusion for Specialty Designation: The basis for the conclusion that both as written and in operation, the processes, evidentiary standards, and factors used to impose the Specialty Drug Designation NQTL on MH/SUD drugs are comparable to and applied no more stringently than the processes, strategies, evidentiary standards, and factors used to impose the NQTL on M/S drugs is the analysis findings as follows. The written materials and minutes analysis revealed that as written factors and standards used for drugs designated as a Specialty drug are the same and are not used differently or more restrictively based on a drug being for M/S or MH/SUD treatment. The review and comparison of the decisions made for the example drugs Zyprexa Relprevv (MH) and Ozurdex (M/S) showed that the sources are different for each drug because the information must be drug specific; however, the sources are found using the same databases and evaluated using the same standards and sources are comparable and standardized regarding the information found therein. The sources of information are not explicit in the minutes but the PBM clinician analyzing the decision can find the sources and standards as described in the process and assess that the process was followed consistently. The source for Zyprexa Relprevv (MH) is the FDA labeling for that drug and its medication guide. The source for Ozurdex (M/S) is the FDA labeling for that drug and patient information resources found for that drug. No more stringent sources are used, and these sources are comparable. The MH drug Zyprexa Relprevv was designated as not specialty, and the drug Ozurdex was designated as specialty. No other MH drugs have decisions that occurred during the previous two years of minutes. No SUD drugs have decisions that occurred during the previous two years of minutes. The process, and evidentiary standards used to apply specialty designation to mental health or substance use disorder are the same and are applied no more stringently than the specialty drug designation decided for drugs used to treat medical or surgical disorders. In operations an analysis of the formulary extract demonstrated that overall, there is a lower percentage of drugs designated as a Specialty drug in the MH and SUD drugs compared to the MED/SURG drugs. Overall, there are no more drugs designated as specialty in MH and SUD compared to MED/SURG drugs.

Advanced Control Formulary 2021 Plan - Aetna Specialty drug designation

- The Medical/Surgical category has 21.5%
- The Mental Health category has 3.5%
- The Substance Use Disorder category has 10.5%

Standard Opt-Out Formulary 2021 Plan – Aetna Specialty drug designation

  - The Medical/Surgical category has 19.4%
  - The Mental Health category has 3.1%
  - The Substance Use Disorder category has 11.1%
- ACF Tier 4: 0% of the 6 Specialty MH medications are preferred while 54.3% (213/392) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)
- SOO Tier 4: 0% of the 6 Specialty MH medications are preferred while 53.5% (206/385) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)

By investigation of the tier placement of MH drugs in Tier 5 vs Tier 4 revealed that factors, standards are the same and sources are drug specific, and standard based on FDA labeling. Further analysis did not reveal that the process is followed more stringently. The process, factors and standards were not used more restrictively to designate more MH drugs as specialty or to place them on Tier 5 instead of Tier 4. The reason for the difference is that more drugs are available in lower tiers for MH conditions than are available to compared M/S example drugs. The process, and evidentiary standards used to apply specialty designation to mental health or substance use disorder are the same, and are applied no more stringently than the specialty drug designation decided for drugs used to treat medical or surgical disorders both as written and in operations. Aetna delegates the Specialty Drug designation to CVS Caremark, except for the purpose of applying a copay or restricting distribution at a specialty pharmacy. This analysis was done by PBM Clinicians, they are pharmacists, and they made no recommendations regarding NQTLs applied to MH/SUD and M/S drugs. No variation in the use of PBM Clinicians for MH/SUD compared to M/S NQTL analyses.

8. Case Management

Case Management is not an NQTL. This section is not applicable. NQTLs are treatment limitations that are not numerical in nature but otherwise may limit the scope or duration of MH/SUD benefits. Case Management is a voluntary service to our members. There are no adverse consequences to the member if a member decides not to enroll or use information provided.

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

B. Identify the factors used in the development of the limitation(s);

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

D. Identify the methods and analysis used in the development of the limitation(s); and

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

9. Process for Assessment of New Technologies

The process for assessment of new technologies is described in **1. Medical Necessity**.

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

B. Identify the factors used in the development of the limitation(s);

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

D. Identify the methods and analysis used in the development of the limitation(s); and

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

10. <u>Standards for Provider Credentialing and Contracting</u>

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits	MH/SUD Benefits
Covered services: Applies to all Med/Surg and MH/SUD benefits delivered in-network, except pharmacy. **Triggers, Timelines, and Forms:** MH/SUD and M/S providers wishing to participate in Aetna's networks submit an application using the Maryland Uniform Credentialing Form. Aetna's credentialing staff verify the information using CMS-approved primary sources and the Council for Affordable Quality Healthcare data warehouse. No provider of any type is permitted to participate in an Aetna network without an active professional license, or if subject to OIG sanctions or OPM debarment, or if listed on a CMS preclusion. MH/SUD and M/S providers are re-credentialed every three years. Aetna also monitors all providers on an ongoing basis for member complaints and concerns about professional conduct and competence. In 2021, the Med/Surg network was open except for 7 specialties in southern Maryland; as of Q42021, all panels are open. The entire Med/Surg network is open in northern Maryland. **Summary of Requirements**: The participation criteria for providers and facilities are set forth in Aetna's **Network Participation Criteria**. Each provider must meet certain core criteria pertaining to qualifications, availability of services, office/facility environment, insurance and professional competence and conduct, as well as additional criteria apply according to the specific type of provider. An Aetna Medical Director or his or her physician-designee is authorized to make exceptions to Board certification, education, DEA	**Covered Services:** Applies to all MH/SUD benefits delivered in-network, except pharmacy. **Triggers, Timelines, and Forms:** MH/SUD and M/S providers wishing to participate in Aetna's networks submit an application using the Maryland Uniform Credentialing Form. Aetna's credentialing staff verify the information using CMS-approved primary sources and the Council for Affordable Quality Healthcare data warehouse. No provider of any type is permitted to participate in an Aetna network without an active professional license, or if subject to OIG sanctions or OPM debarment, or if listed on a CMS preclusion report. MH/SUD and M/S providers are re-credentialed every three years. Aetna also monitors all providers on an ongoing basis for member complaints and concerns about professional conduct and competence. The MH/SUD (Behavioral Health) network is open. **Summary of Requirements**: The participation criteria for providers and facilities are set forth in Aetna's **Network Participation Criteria**. Each provider must meet certain core criteria pertaining to qualifications, availability of services, office/facility environment, insurance and professional competence and conduct, as well as additional criteria apply according to the specific type of provider. An Aetna Medical Director or his or her physician-designee is authorized to make exceptions to Board certification, education, DEA certification, and hospital privileges requirements. The Credentialing & Performance Committee, which is comprised of participating

certification, and hospital privileges requirements. The Credentialing & Performance Committee, which is comprised of participating providers in various specialties including behavioral health, is authorized to make final determinations with respect to exceptions to unencumbered license and professional competence and conduct requirements.

Detailed participation criteria are posted here: **https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/2023-network-participation-criteria-document.pdf**

Plan language: AL SG HCOC-2021-EPO 05

Who provides the care

Just as the starting point for coverage under your plan is whether the services and supplies are **eligible health services**, the foundation for getting covered care is the network. This section tells you about **network providers.**

Network providers

We have contracted with **providers** in the **service area** to provide **eligible health services** to you. These **providers** make up the network for your plan.

For you to receive benefits, you must use **network providers** for **eligible health services**. There are some exceptions:

- **Emergency services** – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section
- Urgent care – refer to the description of **emergency**

providers in various specialties including behavioral health, is authorized to make final determinations with respect to exceptions to unencumbered license and professional competence and conduct requirements.

Detailed participation criteria are posted here: **https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/2023-network-participation-criteria-document.pdf**

Plan language: AL SG HCOC-2021-EPO 05

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Just as the starting point for coverage under your plan is whether the services and supplies are **eligible health services**, the foundation for getting covered care is the network. This section tells you about **network providers.**

Network providers

We have contracted with **providers** in the **service area** to provide **eligible health services** to you. These **providers** make up the network for your plan.

For you to receive benefits, you must use **network providers** for **eligible health services**. There are some exceptions:

- **Emergency services** – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section
- Urgent care – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section and to the schedule of benefits

services and urgent care in the *Eligible health services under your plan* section and to the schedule of benefits • **Network provider** not available without unreasonable delay, travel or does not have the training and expertise to treat your– You can get **eligible health services** under your plan that are provided by an **out-of-network provider** if an appropriate **network provider** is not available without unreasonable delay, travel or does not have the training and expertise to treat your condition. You must ask to use the **out-of-network provider** in advance and we must agree. See the *How to contact us for help* section for assistance. • Transplants-see the description of transplant services in the *Eligible health services under your plan* section You may select a **network provider** from the **directory** through your **Aetna** member website at www.aetna.com. You can search our online **directory** for names and locations of **providers**. You will not have to submit claims for treatment received from **network providers**. Your **network provider** will take care of that for you. And we will directly pay the **network provider** for what the plan owes. Page 97-106 **Health professional** A person who is licensed, certified, registered or otherwise authorized by law to provide health care services to the public. For example, **physicians**, nurses, and physical therapists. **Hospital**	• **Network provider** not available without unreasonable delay, travel or does not have the training and expertise to treat your– You can get **eligible health services** under your plan that are provided by an **out-of-network provider** if an appropriate **network provider** is not available without unreasonable delay, travel or does not have the training and expertise to treat your condition. You must ask to use the **out-of-network provider** in advance and we must agree. See the *How to contact us for help* section for assistance. • Transplants-see the description of transplant services in the *Eligible health services under your plan* section You may select a **network provider** from the **directory** through your **Aetna** member website at www.aetna.com. You can search our online **directory** for names and locations of **providers**. You will not have to submit claims for treatment received from **network providers**. Your **network provider** will take care of that for you. And we will directly pay the **network provider** for what the plan owes. Page 97-106 **Behavioral health provider** An individual professional that is licensed, registered, certified or otherwise authorized by law to provide diagnostic and/or therapeutic services for **mental health disorders** and **substance abuse** under the laws of the jurisdiction where the individual practices. **Health professional** A person who is licensed, certified, registered or otherwise

An institution licensed as a **hospital** by applicable laws and accredited as a **hospital** by The Joint Commission (TJC). **Hospital** does not include a: • Convalescent facility • Rest facility • Nursing facility • Facility for the aged • **Psychiatric hospital** • **Residential treatment facility** for **substance abuse** • **Residential treatment facility** for **mental health disorders** • Extended care facility • Intermediate care facility • **Skilled nursing facility** **Network provider** A **provider** listed in the **directory** for your plan. **Physician** A skilled health care professional trained and licensed to practice medicine under the laws of the state where they practice; specifically, doctors of medicine or osteopathy. Under some plans, a physician can also be a **primary care physician (PCP)**. **Provider** A **physician**, other **health professional**, **hospital**, **skilled nursing facility**, **home health care agency** or other entity or person licensed or certified under applicable law to provide health care services to you. If state law does not specifically provide for licensure or certification, the entity must meet all Medicare accreditation standards (even if it does not participate in Medicare).	authorized by law to provide health care services to the public. For example, **physicians**, nurses, and physical therapists. **Hospital** An institution licensed as a **hospital** by applicable laws and accredited as a **hospital** by The Joint Commission (TJC). **Hospital** does not include a: • Convalescent facility • Rest facility • Nursing facility • Facility for the aged • **Psychiatric hospital** • **Residential treatment facility** for **substance abuse** • **Residential treatment facility** for **mental health disorders** • Extended care facility • Intermediate care facility • **Skilled nursing facility** **Network provider** A **provider** listed in the **directory** for your plan. **Physician** A skilled health care professional trained and licensed to practice medicine under the laws of the state where they practice; specifically, doctors of medicine or osteopathy. Under some plans, a physician can also be a **primary care physician (PCP)**. **Provider** A **physician**, other **health professional**, **hospital**, **skilled nursing facility**, **home health care agency** or other entity or person licensed

	or certified under applicable law to provide health care services to you. If state law does not specifically provide for licensure or certification, the entity must meet all Medicare accreditation standards (even if it does not participate in Medicare). **Psychiatric hospital** An institution specifically licensed or certified as a **psychiatric hospital** by applicable laws to provide a program for the diagnosis, evaluation and treatment of alcoholism, drug abuse, **mental health disorders** (including substance related disorders) or mental **illnesses**. **Residential treatment facility (mental health disorders)** An institution specifically licensed as a **residential treatment facility** by applicable laws to provide for mental health residential treatment programs. **Residential treatment facility (substance abuse)** An institution specifically licensed as a **residential treatment facility** by applicable laws to provide for **substance abuse** residential treatment programs.

B. Identify the factors used in the development of the limitation(s);

Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

- Participation standards and credentialing processes developed by Aetna in accordance with NCQA accreditation requirements for Health Plans and Managed Behavioral Health Organizations
- No other factors were considered and rejected. No factors were weighted more than another.

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

Sources:

Provider Admission (Credentialing) Standards NQTL: Outpatient group and individual providers

- NCQA standards (Aetna is NCQA Health Plan and Managed Behavioral Health Organization Accredited)
- Verification from Aetna, National Committee for Quality Assurance (NCQA) Standards and Guidelines for the Accreditation of Health Plans and CMS approved primary sources**.** Aetna utilizes the Council for Affordable Quality Healthcare (CAQH) data warehouse

Provider Admission (Credentialing) Standards NQTL: Facility and Facility-Based Practitioners

- NCQA standards (Aetna is NCQA Health Plan and Managed Behavioral Health Organization Accredited)
- Facility qualifications are reviewed to ensure facility meets Aetna's established requirements for organizational credentialing, including state licensing board, operating/certificate of occupancy, accreditation entity.

Definitions and evidentiary standards:

- Participation standards and credentialing processes developed by Aetna in accordance with NCQA accreditation requirements for Health Plans and Managed Behavioral Health Organizations. These requirements ensure efficient, accurate, and consistent credentialing, including protecting information, verifying credentials, and ongoing monitoring. Aetna's credentialing department is NCQA certified. Aetna's policies and procedures are described below.

D. Identify the methods and analysis used in the development of the limitation(s); and

The provider admission standards and process are the same between M/S and MH/SUD providers. The variances will only be dependent upon licensing board requirements. Aetna maintains one set of credentialing policies that are equally applicable to MH/SUD and medical/surgical.

MH/SUD and M/S providers wishing to participate in Aetna's networks submit an application with the information required on the Maryland Uniform Credentialing Form. Aetna's credentialing staff verify the information using CMS-approved primary sources and the Council for Affordable Quality Healthcare data warehouse. Where Aetna has delegated credentialing to a third party, the delegate is required to use Aetna's criteria or criteria consistent with Aetna's. No provider of any type is permitted to participate in an Aetna network without an active professional license, or if subject to OIG sanctions or OPM debarment, or if listed on a CMS preclusion report.

The participation criteria for providers and facilities are set forth in Aetna's Network Participation Criteria, linked in **A.**. Each provider must meet certain core criteria pertaining to qualifications, availability of services, office/facility environment, insurance and professional competence and conduct, as well as additional criteria apply according to the specific type of provider. An Aetna Medical Director or his or her physician-designee

is authorized to make exceptions to Board certification, education, DEA certification, and hospital privileges requirements. The Credentialing & Performance Committee, which is comprised of participating providers in various specialties including behavioral health, is authorized to make final determinations with respect to exceptions to unencumbered license and professional competence and conduct requirements.

MH/SUD and M/S providers are re-credentialed every three years, as described in Policy. Aetna also monitors all providers on an ongoing basis for member complaints and concerns about professional conduct and competence.

Network participation standards for MH/SUD and M/S facilities and professional providers are in most cases identical and, where not identical, are comparable (see Network Participation Criteria). Credentialing processes for MH/SUD and M/S providers are established and monitored pursuant to written policies that are equally applicable to both MH/SUD and M/S facilities and professionals.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

The same NCQA and/or state standards are used to define and monitor minimum requirements for network composition, ensure compliance with applicable state and federal regulatory standards, and to ensure compliance with applicable accreditations standards for both M/S and MH/SUD. The provider admission standards and credentialing process are the same between M/S and MH/SUD providers. The variances will only be dependent upon licensing and/or accreditation requirements per facility type.

Network participation standards and credentialing processes for MH/SUD network providers are comparable to, and not more stringent than, for M/S network providers. As detailed in the policies and discussion in the prior steps, the process is the same, including the application form used, the primary source verification, and the review process. The turnaround times and approval rates are similar across MH/SUD and M/S, especially when reviewing a larger data set, as seen in the individual practitioner TAT.

11. <u>Exclusions for Failure to Complete a Course of Treatment</u>

The plan does not exclude benefits for failure to complete a course of treatment. As such this section is not applicable.

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

B. Identify the factors used in the development of the limitation(s);

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

D. Identify the methods and analysis used in the development of the limitation(s); and

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

12. Restrictions that Limit Duration or Scope of Benefits for Services

There are no restrictions on the types of facilities in which members can receive services; however, facilities must be licensed and contracted as outlined in Aetna's provider credentialing policies. This is addressed in **10. Standards for Provider Credentialing and Contracting**.
There are no plan limits on the duration or scope of MH/SUD benefits; however, covered services must be medically necessary as addressed in **1. Medical Necessity**. Medically necessary care is "clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease."

The EPO product requires members to stay in-network, which is a service area where the EPO is licensed to operate. Geographic limitations inherent in an EPO product are not NQTLs imposed by the health plan.

For most services, the Plan restricts the geographic location in which services can be received to the service area. The Plan defines a service area as the geographic area where network providers for the Plan are located. There are some exceptions, such as for emergency services, urgent care, provider availability, and transplants. Enrollees are covered for urgent care obtained from a facility outside of the service area if the health care service cannot be delayed until the enrollee returns to the service area.

Network providers agree to provide timely access to care, however if a network provider is not reasonably available, upon approval, the enrollee can get services from an out-of-network provider.

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

B. Identify the factors used in the development of the limitation(s);

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

D. Identify the methods and analysis used in the development of the limitation(s); and

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

13. **Restrictions for Provider Specialty**

No, other than credentialing requirements for network providers (such NQTL analysis provided above), the plan does not impose restrictions on provider types for covered services. As such this section is not applicable.

There are no restrictions based on the licensure or certification of a health care provider that limit the scope or duration of benefits for services provided under the plan or coverage. Providers must be duly licensed, as verified through the credentialing process, and practicing within the scope of their license. For example, the plan will cover charges for anesthesia only when billed by provider types qualified to administer anesthesia safely to patients. As noted, the comparative analysis related to that type of restriction is included in the NQTL report for provider credentialing. There are no other restrictions.

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

B. Identify the factors used in the development of the limitation(s);

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

D. Identify the methods and analysis used in the development of the limitation(s); and

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

14. <u>Reimbursement for INN Providers, OON Providers, INN Facilities, OON Facilities (separately)</u>

A. Provide the specific plan language for each NQTL in the above defined category and identify the medical/surgical and mental health and/or substance use disorder benefits to which it applies;

Med/Surg Benefits	MH/SUD Benefits
<u>Participating Provider and Facility Reimbursement</u> **Covered services:** Applies to all Med/Surg and MH/SUD non-prescription benefits delivered in-network **Plan language:** ➢ Section # MD 2021 / Form # AL SG HCOC-2021-EPO 05/ Page # 100-101 **Negotiated charge** *For health coverage, this is either:* • The amount a **network provider** has agreed to accept • The amount we agree to pay directly to a **network provider** or third party vendor (including any administrative fee in the amount paid) for providing services, **prescription drugs** or supplies to plan members. This does not include **prescription drug** services from a **network pharmacy**. 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	**<u>Participating Provider and Facility Reimbursement</u>** **Covered services:** Applies to all Med/Surg and MH/SUD non-prescription benefits delivered in-network **Plan language:** ➢ Section # MD 2021 / Form # AL SG HCOC-2021-EPO 05/ Page # 100-101 **Negotiated charge** *For health coverage, this is either:* • The amount a **network provider** has agreed to accept • The amount we agree to pay directly to a **network provider** or third party vendor (including any administrative fee in the amount paid) for providing services, **prescription drugs** or supplies to plan members. This does not include **prescription drug** services from a **network pharmacy**. 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. **Non-Participating Provider and Facility Reimbursement** **Covered services:** Emergency care, transplants, care unavailable in-network as described in the plan language below **Plan language:** For you to receive benefits, you must use **network providers** for **eligible health services**. There are some exceptions: • **Emergency services** – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section • Urgent care – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section and to the schedule of benefits • **Network provider** not available without unreasonable delay, travel or does not have the training and expertise to treat your– You can get **eligible health services** under your plan that are provided by an **out-of-network provider** if an appropriate **network provider** is not available without unreasonable delay, travel or does not have the training and expertise to treat your condition. You must ask to use the **out-of-network provider** in advance and we must agree. See the *How to contact us for help* section for assistance. • Transplants-see the description of transplant services in the *Eligible health services under your plan* section	These arrangements will not change the negotiated charge under this plan. **Non-Participating Provider and Facility Reimbursement** **Covered services:** Emergency care, transplants, care unavailable in-network as described in the plan language below **Plan language:** For you to receive benefits, you must use **network providers** for **eligible health services**. There are some exceptions: • **Emergency services** – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section • Urgent care – refer to the description of **emergency services** and urgent care in the *Eligible health services under your plan* section and to the schedule of benefits • **Network provider** not available without unreasonable delay, travel or does not have the training and expertise to treat your– You can get **eligible health services** under your plan that are provided by an **out-of-network provider** if an appropriate **network provider** is not available without unreasonable delay, travel or does not have the training and expertise to treat your condition. You must ask to use the **out-of-network provider** in advance and we must agree. See the *How to contact us for help* section for assistance. • Transplants-see the description of transplant services in the *Eligible health services under your plan* section

The allowed amount for out-of-network services, for both MH/SUD and M/S, will be at least equal to the allowed amount for in-network services performed by similarly licensed providers in the same geographical region. The member will not be required to pay the balance bill, from applying to charges made by an on-call physician or a hospital-based physician who has accepted assignment in line with Maryland law. Payment for charges of an on-call physician and hospital-based physicians, as described below, will be made within 30 days after receipt of the claim. With respect to a claim for hospital based physician charges made for covered services rendered to an insured, the plan will pay no less than the greater of than the amounts set forth in Section 14.205.2(D)(2)(II) 1 and 2. The plan will calculate the average rate paid to similarly licensed in-network providers who are hospital-based physicians, referenced in Section 14.205.2(D)(2)(II) 1, for the same covered service by summing the contracted rate for all occurrences of the CPT code for that covered service and then dividing by the total number of occurrences of the CPT code.	The allowed amount for out-of-network services, for both MH/SUD and M/S, will be at least equal to the allowed amount for in-network services performed by similarly licensed providers in the same geographical region. The member will not be required to pay the balance bill, from applying to charges made by an on-call physician or a hospital-based physician who has accepted assignment in line with Maryland law. Payment for charges of an on-call physician and hospital-based physicians, as described below, will be made within 30 days after receipt of the claim. With respect to a claim for hospital based physician charges made for covered services rendered to an insured, the plan will pay no less than the greater of than the amounts set forth in Section 14.205.2(D)(2)(II) 1 and 2. The plan will calculate the average rate paid to similarly licensed in-network providers who are hospital-based physicians, referenced in Section 14.205.2(D)(2)(II) 1, for the same covered service by summing the contracted rate for all occurrences of the CPT code for that covered service and then dividing by the total number of occurrences of the CPT code.

B. Identify the factors used in the development of the limitation(s);

Participating Provider Reimbursement

Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

1. Index Rates (e.g. Medicare reimbursement rates)
2. Market dynamics (e.g. supply and demand)
3. Provider type (e.g. MD, NP)
4. Service type (e.g. counseling, initial assessment)

Participating Facility Reimbursement

Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

1. Provider type
2. Scope and complexity of services
3. Service type
4. Index rates
5. Competitive data
6. Market dynamics

Non-Participating Provider and Facility Reimbursement
Factors: *Note: All factors are the same for medical/surgical and MH/SUD*

- State and federal law: State and federal laws prescribe how plans must reimburse OON providers for emergency services or when the member did not voluntarily use OON benefits

No other factors were considered and rejected. No factors were weighted more than another.

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;

Participating Provider Reimbursement
Sources and Processes:

1. **For Index Rates:** CMS RBRVS rates: Aetna's Medical Economics Unit (MEU) identifies the CMS RBRVS rates for the service codes and proposes the AMFS rates as a percentage of the CMS rates. MEU communicates the preliminary rates to network management.
2. **For Market Dynamics:** Network analysis of market dynamics: [redacted]
3. **For Provider Type:** For both MH/SUD and M/S providers, rates are tiered based on provider type/level of training, consistent with CMS methodology.
4. **For Service Type:** Service types are identified by CPT and HCPC codes.

When contracting with a given provider, additional factors may enter into consideration:

Unit Cost [redacted]

Provider leverage: AKA bargaining power. This is generally a function of the relative scarcity of the provider's specialty or area of focus, member needs for that specialty/focus, whether the provider group is a large system or practice group that includes numerous specialties,

plan sponsor demand, the provider's participation with other payors, and any other factors that dictate a provider's ability to negotiate a rate higher [redacted], as well as the number of members the carrier is able to drive to the provider.

No other sources were considered and rejected.

Participating Facility Reimbursement

Sources and Processes:

1. **For Provider Type:** Type of facility (inpatient hospital, ambulatory surgery center, etc.)
2. **For Scope and Complexity of Services:** Range of practice specialties, levels of care and settings offered by the facility
3. **For Service Type:** Service types are identified by CPT and HCPC codes. For facility-based providers, type of service also refers to inpatient or outpatient.
4. **For Index Rates:** Medicare DRGs and Medicare RVRBS rates
5. **For Competitive Data:** To the extent that can be determined from information publicly available through state and federal All Payor Claims Databases. Also includes consultants' analyses of Aetna's discount position in the market compared to other carriers, and what Aetna pays other facilities.
6. **For Market Dynamics:** The local networks [redacted]

When contracting with a given provider, additional factors may enter into consideration:

Unit Cost [redacted]

Provider leverage: AKA bargaining power. This is generally a function of the relative scarcity of the provider's specialty or area of focus, member needs for that specialty/focus, whether the provider group is a large system or practice group that includes numerous specialties, plan sponsor demand, the provider's participation with other payors, and any other factors that dictate a provider's ability to negotiate a rate higher [redacted], as well as the number of members the carrier is able to drive to the provider.

No other sources were considered and rejected.

Evidentiary Standards: The evidentiary standard for index rates used in setting [redacted] is the CMS Resource Based Relative Value Scale (RBRVS) payment system. Those CMS rates are used [redacted]

[redacted].

Non-Participating Provider Reimbursement
State and federal law: The member will not be required to pay the balance bill, from applying to charges made by an on-call physician or a hospital-based physician who has accepted assignment in line with Maryland law. Payment for charges of an on-call physician and hospital-based physicians, as described below, will be made within 30 days after receipt of the claim.

With respect to a claim for hospital based physician charges made for covered services rendered to an insured, the plan will pay no less than the greater of than the amounts set forth in Section 14.205.2(D)(2)(II) 1 and 2. The plan will calculate the average rate paid to similarly licensed in-network providers who are hospital-based physicians, referenced in Section 14.205.2(D)(2)(II) 1, for the same covered service by summing the contracted rate for all occurrences of the CPT code for that covered service and then dividing by the total number of occurrences of the CPT code.

Evidentiary Standards: CMS Medicare rates; average rates from HMO paid claims

Non-Participating Facility Reimbursement
State and federal law: State and federal laws prescribe how plans must reimburse OON providers for emergency services or when the member did not voluntarily use OON benefits. The factor is the source. The HMO will pay a claim submitted by a facility at the rate approved by the Health Services Cost Review Commission (HSCRC). These rates are loaded for Aetna's claim processing system to access. Other than those hospital services regulated by the HSCRC, the source is the FAIR Health database or CMS Medicare rates. No other sources were considered and rejected.

Evidentiary Standards: Rates approved by the Health Services Cost Review Commission; FAIR Health database of charges made by providers in the geographic area; CMS Medicare rates

D. Identify the methods and analysis used in the development of the limitation(s); and

Participating Provider Reimbursement

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 rates [redacted]; and (2) contracting with providers. Below is a summary of the comparability and stringency analysis for each step.

(1) In developing and refreshing the rates, the Plan uses comparable factors, strategies, processes and evidentiary standards for MH/SUD and M/S services, both as written and in operation. [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. [redacted]

Participating Facility Reimbursement

The factors, strategy, processes and evidentiary standards for determining reimbursement for MH/SUD facility-based providers are comparable to M/S facility-based providers [redacted]

[redacted]

Non-Participating Provider and Facility Reimbursement

Non-participating providers and facilities are reimbursed for eligible services for HMO members in accordance with the methodologies set forth in state law regarding non-participating provider and facility reimbursement.

E. Provide any evidence and documentation to establish that the limitation(s) is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits.

Aetna maintains one policy on rate development, [redacted]

MHPAEA Data Report for Calendar Year Ending December 31, 2021 (§15–144(f))

Health Plan	14042142 - MD Silver OAEPO 2500 90% HSA T - Off Exchange

Benefit	Classification	# of Authorization Requests	# of Authorization Requests	# of Authorization Requests Denied	% Approved	% Denied
Mental Health Benefits	INN-Inpatient	1	1	0	100%	0%
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	1	1	0	100%	0%
	INN-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	INN-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!
Substance Use Disorder Benefits	INN-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	0	0	0	#DIV/0!	#DIV/0!
	INN-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	INN-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!
Medical /Surgical Benefits	INN-Inpatient	7	6	1	86%	14%
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	7	7	0	100%	0%
	INN-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	INN-Outpatient-AllOther	1	1	0	100%	0%
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!

Benefit	Classification	# of Claims	# of Claims	# of Claims	% Approved	% Denied	Reasons for Denial of
Mental Health Benefits	INN-Inpatient	7	6	1	86%	14%	V64
	OON-Inpatient	1	0	1	0%	100%	
	Emergency Services	5	3	2	60%	40%	RC1 V64
	RX	138	102	36	69%	31%	85, 21, 13, 870
	INN-Outpatient-Office	32	26	6	81%	19%	011 780 R11 T01
	OON-Outpatient-Office	1	0	1	0%	100%	11
	INN-Outpatient-AllOther	49	40	9	82%	18%	011 770
	OON-Outpatient-AllOther	3	0	3	0%	100%	

Substance Use Disorder Benefits	**INN-Inpatient**	0	0	0	#DIV/0!	#DIV/0!	
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!	
	Emergency Services	1	1	0	100%	0%	
	RX	17	9	8	53%	47%	76, 7X, 22
	INN-Outpatient-Office	2	2	0	100%	0%	
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!	
	INN-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!	
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!	
Medical /Surgical Benefits	**INN-Inpatient**	78	49	29	63%	37%	782 839 HHG Q28 T00 V64 W91 Z10
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!	
	Emergency Services	9	4	5	44%	56%	782 839 HHG
	RX	639	452	187	69%	31%	85, 21, 13, 870
	INN-Outpatient-Office	499	452	47	91%	9%	011 124 463 483 607 717 770
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!	
	INN-Outpatient-AllOther	437	407	30	93%	7%	011 480 607 712 717
	OON-Outpatient-AllOther	1	0	1	0%	100%	376