MHPAEA Summary Form

Under a federal law called the Mental Health Parity and Addiction Equity Act (MHPAEA), Aetna Life Insurance Co. 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 Life Insurance Co. 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 NQTL’s 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;

   **Covered services:** All inpatient, outpatient and emergency care medical/surgical and mental health and/or substance use disorder services

   **Plan language:**
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.
- For in-network coverage, 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.

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
MHPAEA Summary Form

- 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);

Medical necessity applies to all medical/surgical and mental health/substance use disorder benefits in each MHPAEA category and is based on generally accepted standards of care.

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

Note—“Processes”, “strategies”, “evidentiary standards”, and “other factors” are terms of equivalence; none of which have to be individually articulated in order to be sufficient NQTL analysis. A plain reading interpretation of the MHPAEA Final Rule makes it clear that “any” (emphasis added) processes, strategies, evidentiary standards, or other factors” used in applying the MH/SUD NQTL can be compared to any process, strategy, evidentiary standard, or other factors used in applying the medical/surgical NQTL for the purposes of comparability and stringency analysis. See 29 CFR 2590.712(c)(4). Therefore, throughout a portion of these answers you will see content populated as both a process, strategy, or evidentiary standard—some of which may be supported qualitatively or some of which may be supported quantitatively (e.g. “cost” as a factor to add a service to the NPL).

MHPAEA provides that a plan may develop medical policies that limit care for mental health/substance use disorder benefits based on medical necessity as long as it does so for medical/surgical benefits and the “evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition”. 45 CFR 146.136(c)(4)(iii) (Example 4). The processes, strategies, and evidentiary standards include:

- 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

Review of generally accepted national quality standards, i.e.) National Committee for Quality Assurance, NQCA

Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations such as:

- Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Medicare Benefit Policy Manual
- MCG guidelines
- Applied Behavior Analysis Medical Necessity Guide
- InterQual guidelines (as required by contractual provisions)
- Level of Care Utilization System (LOCUS) for adults 18 years old and above and the Child and Adolescent Level of Care Utilization System/Child and Adolescent Service Intensity Instrument (CALOCUS/CASII)

These processes, strategies, and evidentiary standards are represented in Aetna Clinical Policies and in our published Aetna Clinical Policy Bulletins (CPBs) (https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)

In determining whether a medical technology is medically necessary and established, the Clinical Policy Council will consider whether the following five criteria are met:

- Whether the medical technology has final approval from the appropriate governmental regulatory bodies
- Whether the scientific evidence permits conclusions about the effect of the medical technology on health outcomes
- Whether the medical technology improves net health outcomes
- Whether the medical technology is at least as beneficial as any established alternatives
- Whether the medical technology is more costly (taking into account all health expenses incurred in connection with the medical technology) than any equally effective established alternatives

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

Refer to Section 1C.
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.

As written: 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 clinician with coverage determinations.

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. 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. 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.

For medical treatments Aetna utilizes Milliman Care Guidelines (MCG) as a guideline to determine the medical necessity.

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.

The Clinical Policy council is comprised of pharmacists and medical directors from the Medical Policy Administration (MPA) department, National Accounts department, Behavioral Health department, Clinical Pharmacy department and regional Patient Management units. The Clinical Policy council usually convenes twice monthly.

In operation: See Section 2E. Prior Authorization Review Process as medical necessity is a component of the utilization review process.

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;

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.
MHPAEA Summary Form

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

For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) http://www.aetna.com/healthcare-professionals/assets/documents/MH/SUD_precert_list.pdf

Plan language:
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.
- For in-network coverage, 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.

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 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.

Out-of-network: When you go to an out-of-network provider, you are responsible to obtain precertification from us for any services and supplies on the precertification list. If you do not precertify, your benefits may be reduced, or the plan may not pay. See your schedule of benefits for this information. The list of services and supplies that require precertification appears later in this section. Also, for any precertification benefit reduction that is applied, see the schedule of benefits Precertification benefit reduction section.
You should get **precertification** within the timeframes listed below. For emergency services, **precertification** is not required, but you should notify us within the timeframes listed below. In addition, **precertification** will not be denied on the basis of late notification from a hospital, if your condition prevented the hospital from knowing your state or our emergency notice process. To obtain **precertification**, call us at the telephone number listed on your ID card. A representative is available 24 hours a day, 7 days a week. This call must be made:

<table>
<thead>
<tr>
<th>You, your physician or the facility will:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Call and request <strong>precertification</strong> at least 14 days before the date you are scheduled to be admitted.</td>
<td>For non-emergency admissions</td>
</tr>
<tr>
<td>Call within 48 hours or as soon as reasonably possible after you have been admitted.</td>
<td>For an emergency admission</td>
</tr>
<tr>
<td>Call before you are scheduled to be admitted. An urgent admission is a hospital admission by a physician due to the onset of or change in an illness, the diagnosis of an illness, or an injury.</td>
<td>For an urgent admission</td>
</tr>
<tr>
<td>Call at least 14 days before the outpatient care is provided, or the treatment or procedure is scheduled.</td>
<td>For outpatient non-emergency medical services requiring <strong>precertification</strong></td>
</tr>
</tbody>
</table>

We will tell you and your physician in writing of the **precertification** decision, where required by state law. If your **precertified** services are approved, the approval is valid for 180 days as long as you remain enrolled in the plan.

When you have an inpatient **stay** in a facility, we will tell you, your physician and the facility about your **precertified** length of **stay**. If your physician recommends that your **stay** be extended, additional days will need to be **precertified**. You, your physician, or the facility will need to call us at the number on your ID card as soon as reasonably possible, but no later than the final authorized day. We will review and process the request for an extended **stay**. We will tell you and your physician in writing of an approval or denial.

If **precertification** determines that the **stay** or services and supplies are not **covered benefits**, we will explain why and how our decision can be appealed. You or your **provider** may request a review of the **precertification** decision. See the *When you disagree - claim*
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 if you don’t obtain the required precertification?

If you don’t obtain the required precertification:

- Your benefits may be reduced, or the plan may not pay any benefits. See the schedule of benefits Precertification benefit reduction section.
- You will be responsible for the unpaid balance of the bills.
- Any additional out-of-pocket expenses you have will not count toward your out-of-network deductible or maximum out-of-pocket limit if there are any.

What types of services require precertification?

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

<table>
<thead>
<tr>
<th>Inpatient services and supplies</th>
<th>Outpatient services and supplies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stays in a hospital</strong></td>
<td>Complex imaging</td>
</tr>
<tr>
<td><strong>Stays in a skilled nursing facility</strong></td>
<td>Comprehensive infertility services</td>
</tr>
<tr>
<td><strong>Stays in a rehabilitation facility</strong></td>
<td>Cosmetic and reconstructive surgery</td>
</tr>
<tr>
<td><strong>Stays in a hospice facility</strong></td>
<td>Non-emergency transportation by fixed wing airplane</td>
</tr>
<tr>
<td><strong>Stays in a residential treatment facility for treatment of mental health disorders and substance abuse</strong></td>
<td>Injectables, (immunoglobulins, growth hormones, Multiple Sclerosis medications, Osteoporosis medications, Botox, Hepatitis C medications)</td>
</tr>
<tr>
<td>Bariatric (obesity) surgery</td>
<td>Kidney dialysis</td>
</tr>
</tbody>
</table>
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.

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);
MHPAEA Summary Form

- 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

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.

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.

Precertification covered benefit reduction

Your booklet-certificate contains a complete description of the precertification program. You will find details on precertification in the Medical necessity and precertification requirements section.

If you don’t get precertification of your eligible health services when required, this plan will reduce by 50% up to $400 per service or supply for each type of eligible health service.

Sequenced Treatment

Sequenced treatment generally refers to application of evidenced based guidelines that recommend use of the most effective forms of treatment first, moving to less effective ones if the highest rated treatments are not working for a specific patient. Certain BH and medical/surgical services (detailed below) are subject to sequenced treatment protocols as part of the medical necessity review.

Covered Services:

For Medical/Surgical: Back Pain Invasive Procedures, Spinal Surgery, Total Hip Replacement, Laminoplasty, Obesity Surgery, Vagus Nerve Stimulation, Spinal Cord Stimulation, Deep Brain Stimulation, Urinary Incontinence, Sleep latency testing, Obstructive Sleep Apnea, Feeding programs

For MH/SUD: Transcranial Magnetic Stimulation (TMS), Gender reassignment

Plan language: Same as Medical Necessity Plan language
Treatment Plan Requirement
A treatment plan is an individualized plan of care; where specific target behaviors are clearly defined; frequency, rate, symptom intensity or duration, or other objective measures of baseline levels are recorded, and quantifiable criteria for progress are established. Certain BH and medical/surgical services (detailed below) require the inclusion of a treatment as part of the medical necessity review.

Covered Services:
For Medical/Surgical: Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, Proton beam therapy, Physical Therapy, Occupational Therapy, Speech Therapy
For MH/SUD: Applied Behavior Analysis (ABA)

Plan language:

Autism spectrum disorder
Autism spectrum disorder is defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

Eligible health services include the services and supplies provided by a physician or behavioral health provider for the diagnosis and treatment of autism spectrum disorder. We will only cover this treatment if a physician or behavioral health provider orders it as part of a treatment plan.

We will cover certain early intensive behavioral interventions such as applied behavior analysis. Applied behavior analysis is an educational service that is the process of applying interventions:

- That systematically change behavior
- That are responsible for observable improvements in behavior

Short-term cardiac and pulmonary rehabilitation services
Eligible health services include the cardiac and pulmonary rehabilitation services listed below.

Cardiac rehabilitation
Eligible health services include cardiac rehabilitation services for individuals who have been diagnosed with significant cardiac disease, or who have suffered a myocardial infarction, or have undergone invasive cardiac treatment immediately preceding referral for cardiac rehabilitation. Cardiac rehabilitation is a comprehensive program involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. Covered benefits include:

- Continuous EKG telemetric monitoring during exercise, EKG rhythm strip with interpretation, physician’s revision of exercise prescription, and follow up examination for physician to adjust medication or change regimen; and
- Increased outpatient rehabilitation services (physical therapy, speech therapy and occupational therapy) for cardiac rehabilitation of 90 visits per therapy per plan year.

Pulmonary rehabilitation

Eligible health services include pulmonary rehabilitation services (one (1) program per lifetime) for individuals who have been diagnosed with significant pulmonary disease.

Cardiac and pulmonary rehabilitation services must be provided at a place of service equipped and approved to provide cardiac and pulmonary rehabilitation.

Benefits will not be provided for maintenance programs. Maintenance programs consist of activities that preserve the individual’s present level of function and prevent regression of that function. Maintenance begins when the therapeutic goals of a treatment plan have been achieved, or when no additional progress is apparent or expected to occur.

Short-term rehabilitation services

Short-term rehabilitation services help you restore or develop skills and functioning for daily living. Eligible health services include short-term rehabilitation services your physician prescribes. The services have to be performed by a:

- Licensed or certified physical, occupational or speech therapist
- Hospital, skilled nursing facility or hospice facility
- Home health care agency
- Physician

Short-term rehabilitation services have to follow a specific treatment plan ordered by your physician.

Short-term physical, speech and occupational therapy services provided in an outpatient setting are subject to the same conditions and
limitations for outpatient short-term rehabilitation services. See the Short-term rehabilitation services section in the schedule of benefits.

**Outpatient cognitive rehabilitation, physical, occupational and speech therapy**

**Eligible health services** include:

- Physical therapy, but only if it is expected to significantly improve or restore physical functions lost as a result of an acute illness, injury or surgical procedure.
- Occupational therapy (except for vocational rehabilitation or employment counseling), but only if it is expected to:
  - Significantly improve, develop or restore physical functions you lost as a result of an acute illness, injury or surgical procedure.
  - Relearn skills so you can significantly regain your ability to perform the activities of daily living on your own.
- Speech therapy, but only if it is expected to:
  - Significantly improve or restore the speech function or correct a speech impairment as a result of an acute illness, injury or surgical procedure.
  - Improve delays in speech function development caused by a congenital or genetic birth defect.

Speech function is the ability to express thoughts, speak words and form sentences. Speech impairment is difficulty with expressing one’s thoughts with spoken words.

- Cognitive rehabilitation associated with physical rehabilitation, but only when:
  - Your cognitive deficits are caused by neurologic impairment due to trauma, stroke, or encephalopathy.
  - The therapy is coordinated with us as part of a treatment plan intended to restore previous cognitive function.

**Chiropractic care**

**Eligible health services** include but are not limited to spinal manipulation to correct a muscular or skeletal problem. Benefits will be provided for medically necessary chiropractic services when provided by a licensed chiropractor, doctor of osteopathy (DO) or other eligible practitioner in an office, outpatient department of a hospital/clinic or provider’s office located in a hospital or hospital clinic.

Your provider must establish or approve a treatment plan that details the treatment and specifies frequency and duration.

**Habilitation therapy services**
Habilitation therapy services are services and devices that help you keep, learn, or improve skills and functioning for daily living (e.g. therapy for a child who isn’t walking or talking at the expected age).

**Eligible health services** include habilitation therapy services your physician prescribes. The services have to be provided by a:

- Licensed or certified physical, occupational or speech therapist
- Hospital, skilled nursing facility or hospice facility
- Home health care agency
- Physician

Habilitation therapy services have to follow a specific treatment plan ordered by your physician.

**Outpatient physical, occupational, and speech therapy**

**Eligible health services** include:

- Physical therapy (except for services provided in an educational or training setting), if it is expected to develop any impaired function
- Occupational therapy (except for vocational rehabilitation or employment counseling or services provided in an educational or training setting), if it is expected to develop any impaired function
- Speech therapy (except for services provided in an educational or training setting or to teach sign language), provided the therapy is expected to develop speech function as a result of delayed development

Speech function is the ability to express thoughts, speak words and form sentences.

For members who are 20 years old or younger, benefits for habilitative services will include services for:

- Cleft lip and cleft palate
- Orthodontics
- Oral surgery
- Otologic
MHPAEA Summary Form

- Audiological
- Speech therapy, physical therapy, and occupational therapy

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

**Precertification/Prior Authorization:**
A detailed analytical framework is not provided for the Inpatient prior authorization NQTL because this NQTL applies to all non-palliative procedures, services, devices, and therapies in this classification for both medical/surgical and MH/SUD; as such administration of this NQTL is identical.

*In-network services:* Factors used in the development of the initiation of the precertification NQTL for outpatient / all other benefit classification are listed below. Note: All factors are the same for medical/surgical and MH/SUD. All medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL meet one or more of the following review methodologies specific to each of the identified factors:

- **Cost:** Cost of treatment is satisfied when the average paid Medicare rate was at least $150 for the service being considered (based on Aetna's national paid Medicare claims experience)
- **High cost growth:** High cost growth is satisfied when internal claims data demonstrates that the cost (per member per month) for the procedure, service, device, or therapy increased >10% in the most recent two-year period
- **Variability in costs, length of treatment, or overall number of services for treatment:** Variability in cost and practice is satisfied when 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
- **Evidence-based criteria:** There must be at least one EBC tool available to assist clinicians with precertification decisions. EBC may be sourced from national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies, or criteria from professional associations
- **A procedure, drug, or technology cannot feasibly be managed by claim rules alone due to either subjectivity or complexity of criteria:** Administrative inability to apply Claims Rules (Claims Rules are automated claims system controls that decide if coverage criteria is met).

*Out-of-network services:* Factors used in the development of the initiation of the precertification NQTL for outpatient / all other benefit classification are listed below. Note: All factors are the same for medical/surgical and MH/SUD
MHPAEA Summary Form

- Frequency of services being administered on an OON basis
- Duration of the typical course of treatment

**Sequenced Treatment:**
Note: all factors are the same for medical/surgical and MH/SUD
- Treatment efficacy based on evidence-based criteria (EBC). Evidenced based medicine is an approach to medical practice intended to optimize decision making by emphasizing the use of evidence from well-designed and well-conducted research.
- There must be at least one EBC tool available to assist clinicians with determinations related to sequenced treatment use. EBC may be sourced from (as noted above) national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies or criteria from professional associations.

**Treatment Plan Requirement:**
Note: all factors are the same for medical/surgical and MH/SUD
- Treatment efficacy based on evidence-based criteria (EBC).
Evidenced based medicine is an approach to medical practice intended to optimize decision making by emphasizing the use of evidence from well-designed and well-conducted research.
- There must be at least one EBC tool available to assist clinicians with determinations related to sequenced treatment use. EBC may be sourced from (as noted above) national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies or criteria from professional associations.

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

**Precertification/Prior Authorization:**
A detailed analytical framework is not provided for the Inpatient prior authorization NQTL because this NQTL applies to all non-palliative procedures, services, devices, and therapies in this classification for both medical/surgical and MH/SUD; as such administration of this NQTL is identical.

*In-network services:*
The processes, strategies, and evidentiary standards used to define the factors include the following:

The methods and analysis used in the development of the precertification NQTL include:
- Review of Medicare rates
- Internal claims database analysis

18
Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations such as:

- Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Medicare Benefit Policy Manual
- MCG guidelines
- National Comprehensive Cancer Network NCCN guidelines (Category 1 and 2A recommendations)
- American Society of Addiction Medicine (ASAM) Criteria; Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, most recent version
- Applied Behavior Analysis Medical Necessity Guide
- InterQual guidelines (as required by contractual provisions)
- The Level of Care Utilization System (LOCUS) & Children and Adolescent Level of Care Utilization System (CALOCUS)
- Review of generally accepted national quality standards, i.e.) National Committee for Quality Assurance, NCQA
- Internal claims system review. Review of claims systems capabilities with Head of Operations to validate system functionality.

Availability of EBC exists for all the services on the NPL (via Aetna Clinical Policy Bulletins (CPBs) (https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)

- Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Medicare Benefit Policy Manual
- MCG guidelines
- National Comprehensive Cancer Network NCCN guidelines (Category 1 and 2A recommendations)
- InterQual guidelines (as required by contractual provisions)
- The Level of Care Utilization System (LOCUS) & Children and Adolescent Level of Care Utilization System (CALOCUS)

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

Out-of-network services:

The processes, strategies, and evidentiary standards used to define the factors include the following:

The methods and analysis used in the development of the precertification NQTL include internal claims database analysis.
Sequenced Treatment: Evidence based guidelines and or criteria exist for all medical/surgical and MH/SUD uses of sequenced treatment.
• Availability of EBC exist for all of these services via Aetna Clinical Policy Bulletins (CPBs) CPB numbers for the one BH/SUD sequenced treatment noted and for all of the Medical Surgical sequenced treatments listed are noted and are available publicly at: aetna.com/health-care-professionals/clinical-policy-bulletins.html and are noted below.
• Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations including: the NIMH sequenced treatment alternatives to relieve Depression (STAR*D Study), and an American Psychiatric Association (APA) practice guideline on major depression (2010, reaffirmed 2015).

Treatment Plan Requirement: Evidence based guidelines and or criteria exist for all medical/surgical and MH/SUD uses of treatment plans to establish medical necessity.
• Availability of EBC exist for all of these services via Aetna Clinical Policy Bulletins (CPBs) CPB numbers for the one BH/SUD treatment plan required service noted and for all of the Medical Surgical treatment plan required services are noted and are available publicly at: aetna.com/health-care-professionals/clinical-policy-bulletins.html and are noted below.
• Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations including:
  - Behavior Analyst Certification Board’s Applied Behavior Analysis Treatment of Autism Spectrum Disorder: Practice Guidelines for Healthcare Funders and Managers

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

Refer to Section 2C.

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.

As written:

Precertification/Prior Authorization:
MHPAEA Summary Form

A detailed analytical framework is not provided for the Inpatient prior authorization NQTL because this NQTL applies to all non-palliative procedures, services, devices, and therapies in this classification for both medical/surgical and MH/SUD; as such administration of this NQTL is identical.

**In-network services:**
MH/SUD and medical/surgical Precertification/Concurrent/and Retrospective Review all share the same definition in our standard Certificate of coverage. Additionally, Aetna maintains one set of UM policies that are equally applicable to MH/SUD and medical/surgical.

- A review of Medicare rates demonstrates that all procedure, service, device, and therapy added to the NPL in 2021 met the cost threshold of $150
- Confirmation of evidence-based guidelines and criteria for all Medical Surgical and MH/SUD procedures, services, devices and therapies subject to the precertification NQTL and review of those guidelines demonstrates that a consistent methodology for the pre-certification NQTL was developed and applied, in policy and practice, comparably and no more stringently with respect to MH/SUD benefits than those applied to medical surgical benefits
- Assessment concludes that claims administration procedures cannot be implemented to administer the medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL due to subjectivity or complexity.

**Out-of-network services:**
MH/SUD and medical/surgical Precertification/Concurrent/and Retrospective Review all share the same definition in our standard Certificates of coverage. Additionally, Aetna maintains one set of UM policies that are equally applicable to MH/SUD and medical/surgical.

As it relates to medical/surgical out-of-network utilization and average visits per member data, the medical/surgical services on the out-of-network precertification list all have the highest out-of-network utilization and average visits per member per year numbers compared to other medical/surgical Outpatient All Other services that are not on the out-of-network precertification list (with slight exception of gastric bypass which has an average visits per member per year that is more in line with other medical/surgical Outpatient All Other benefits that are not on the out-of-network precertification list).

**Sequenced Treatment:** Confirmation of evidence-based guidelines and criteria found in the specified CPBs for all Medical Surgical and MH/SUD procedures, services, devices and therapies including sequenced treatment and review
of those guidelines demonstrates that a consistent methodology, which is aligned to generally accepted practice standards, was applied to the development of this NQTL. The MH/SUD benefits for which sequenced treatment requirements apply are no more stringent than those applied to medical surgical benefits. The Clinical Policy Bulletin (CPB) evidence-based guidelines used in the sequenced treatment requirements for medical surgical back pain invasive procedures, spinal surgery, total hip replacement and laminoplasty, obesity surgery, Vagus Nerve Stimulation, Spinal Cord Stimulation, Deep Brain Stimulation, Urinary incontinence procedures as well as those used for gender reassignment and TMS undergo a comprehensive review process and 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.

**Treatment Plan Requirement:** Confirmation of evidence-based guidelines and criteria found in the specified CPBs for all Medical Surgical and MH/SUD procedures, services, devices and therapies including treatment plan requirement and review of those guidelines demonstrates that a consistent methodology, which is aligned to generally accepted practice standards, was applied to the development of this NQTL. The MH/SUD benefits for which treatment plan requirements apply are no more stringent than those applied to medical surgical benefits. The CPBs used in the Treatment Plan requirements that relates to Cardiac Rehabilitation, Proton Beam, Physical Therapy, Occupational Therapy, Speech Therapy, Hyperbaric oxygen therapy, and Applied Behavior Analysis 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.

**In operation:**

**Precertification/Prior Authorization:**
A detailed analytical framework is not provided for the Inpatient prior authorization NQTL because this NQTL applies to all non-palliative procedures, services, devices, and therapies in this classification for both medical/surgical and MH/SUD; as such administration of this NQTL is identical.

**In-network services:**
Aetna monitors the application of the precertification NQTL through several initiatives:
MHPAEA Summary Form

• Mental Health Parity Task Force: Multi-disciplinary team that meets bi-weekly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.
• Denial Rates: comparative rate of MH/SUD vs. medical/surgical denials due to precertification/concurrent reviews. Book of Business data will be formally reviewed by the Parity Task Force at least annually.
• Internal Quality Reviews and Inter-Rater Reliability assessments: Clinical denials due to precertification reviews are conducted randomly throughout the year by Aetna’s Clinical Services Team. The Parity Task Force will review the results of these audits at least annually.
• Average length of stay (ALOS) reviews: comparative ALOS of MH/SUD vs. medical/surgical cases. Book of Business data will be formally reviewed by the Parity Task Force at least annually.
• Complaints and appeals: Aetna’s National Quality Oversight Committee, NQOC tracks and reviews trend rates of complaints and appeals at least annually. The Parity Task Force will review the results of these reviews at least annually.
• Annual surveys: Comparative analysis of (Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, Qualified Health Plan Enrollee Experience Survey, Aetna BH Practitioner Experience Survey, Aetna BH Provider (Facility) Experience Survey, Aetna BH Member Experience Survey, Physician Practice Survey and surveys
• Review of NPL Committee Minutes

Out-of-network services:
Aetna monitors the application of the precertification NQTL through several initiatives:
• Mental Health Parity Task Force: Multi-disciplinary team that meets bi-weekly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.
• Denial Rates: comparative rate of MH/SUD vs. medical/surgical denials due to precertification/concurrent reviews. Book of Business data will be formally reviewed by the Parity Task Force at least annually.
• Internal Quality Reviews and Inter-Rater Reliability assessments: Clinical denials due to precertification reviews are conducted randomly throughout the year by Aetna’s Clinical Services Team. The Parity Task Force will review the results of these audits at least annually.
MHPAEA Summary Form

• Average length of stay (ALOS) reviews: comparative ALOS of MH/SUD vs. medical/surgical cases. Book of Business data will be formally reviewed by the Parity Task Force at least annually.
• Complaints and appeals: Aetna’s National Quality Oversight Committee, NQOC tracks and reviews trend rates of complaints and appeals at least annually. The Parity Task Force will review the results of these reviews at least annually.
• Annual surveys: Comparative analysis of (Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, Qualified Health Plan Enrollee Experience Survey, Aetna BH Practitioner Experience Survey, Aetna BH Provider (Facility) Experience Survey, Aetna BH Member Experience Survey, Physician Practice Survey and surveys

Sequenced Treatment: Audits demonstrating application of these sequenced treatment requirements available upon request.

Treatment Plan Requirement: Audits demonstrating application of these treatment plan requirements available upon request.

We apply the appropriate clinical criteria/guidelines and clinical judgment to the coverage determination. We allow discretion for making authorization decisions based on the professional scope of practice and clinical experience. See stringency controls above in support of the case that discretion does not arbitrarily disadvantage BH/SUD benefits.

3. Concurrent 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;

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

24
MHPAEA Summary Form

For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) http://www.aetna.com/healthcare-professionals/assets/documents/MH/SUD_precert_list.pdf

Plan language:

**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.

**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);

All inpatient services, whether BH or medical/surgical, are subject to Concurrent Review; as such comparability analysis is not required. The factors used for outpatient-all other are identical for both M/S and BH/SUD and are the same as those subject to the Precertification NQTL. Refer to Section 2B. Prior Authorization Review Process, Precertification/Prior Authorization.
MHPAEA Summary Form

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;
   Refer to Section 2C. Prior Authorization Review Process, Precertification/Prior Authorization.

D. Identify the methods and analysis used in the development of the limitation(s); and
   Refer to Section 2C. Prior Authorization Review Process, Precertification/Prior Authorization.

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.
   Refer to Section 2E. Prior Authorization Review Process, Precertification/Prior Authorization.

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;
   Covered services: All emergent inpatient medical/surgical and MH/SUD services/ procedures not precertified for providers on the Late Notification Deviation list or Internal or External Disaster Deviation List
   Plan language: No reference

B. Identify the factors used in the development of the limitation(s);
   Retrospective review for in-network providers is not a limitation; rather a benefit to providers who otherwise would have had their claims administratively denied. For out-of-network retrospective review, refer to Section 2B. Prior Authorization Review Process as the NQTL analytical framework follows the out-of-network precertification factors.

C. Identify the sources (including any processes, strategies, or evidentiary standards) used to evaluate the factors identified above;
   For out-of-network retrospective review, refer to Section 2C. Prior Authorization Review Process as the NQTL analytical framework follows the out-of-network precertification sources.
D. Identify the methods and analysis used in the development of the limitation(s); and

Refer to Section 4C.

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.

For out-of-network retrospective review, refer to Section 2E. Prior Authorization Review Process as the NQTL analytical framework follows the out-of-network precertification factors and sources.
5. **Emergency Services**

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;

   This entire section is not applicable as Emergency Services NQTL reporting is incorporated within the NQTL category analysis.

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

   Not applicable

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

   Not applicable

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

   Not applicable

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.

   Not applicable
6. **Pharmacy Services**

   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;

<table>
<thead>
<tr>
<th>Pharmacy Prior Authorization:</th>
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<tbody>
<tr>
<td>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.</td>
<td>See the NQTL’s Applicable to Med/Surg Benefits response as there are no non-comparable inconsistencies or differences in the application, as written and in operation, of the Pharmacy Prior Authorization NQTL practices between medical/surgical and MH/SUD.</td>
</tr>
</tbody>
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<tr>
<th>Pharmacy Step Therapy (ST):</th>
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<tbody>
<tr>
<td>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.</td>
<td>See the NQTL’s Applicable to Med/Surg Benefits response as there are no non-comparable inconsistencies or differences in the application, as written and in operation, of the Pharmacy Step Therapy NQTL practices between medical/surgical and MH/SUD.</td>
</tr>
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<tr>
<th>Pharmacy Quantity Limits (QL):</th>
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</tr>
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<tbody>
<tr>
<td>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 generally apply to both generic and brand drugs.</td>
<td>See the NQTL’s Applicable to Med/Surg Benefits response as there are no non-comparable inconsistencies or differences in the application, as written and in operation, of the Pharmacy Quantity Limits NQTL practices between medical/surgical and MH/SUD.</td>
</tr>
</tbody>
</table>
Pharmacy prior authorization, pharmacy step therapy, and pharmacy quantity limit programs are applicable for consideration to all medical/surgical benefits or all MH/SUD pharmacy prescription benefits.

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

**Pharmacy Prior Authorization:**

The same factors are considered when establishing pharmacy Prior Authorization for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- 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 Step Therapy:**

The same factors are considered when establishing Step Therapy for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- 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
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- Availability of therapeutic alternatives, including generics, used to treat the same condition

**Pharmacy Quantity Limits:**
The same factors are considered when establishing pharmacy Quantity Limits for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- 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
  - 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

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

**Pharmacy Prior Authorization:**
In the development of pharmacy prior authorization CVS Caremark utilizes sources and evidentiary standards supported by adequate levels of evidence for drug use, safety, efficacy and place in therapy. The same sources and evidentiary standards are considered when establishing pharmacy Prior Authorization for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- FDA product labeling
- Published peer-review clinical literature
- Approved drug compendia
- Accepted clinical practice guidelines, consensus statements, or comparable publications
- Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
MHPAEA Summary Form

- Appropriate clinical drug information from other sources as applicable
- Comparison of similar drugs in terms of safety and efficacy
- Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
- 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
- Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

Pharmacy Step Therapy:

In the development of Pharmacy Step Therapy, CVS Caremark utilizes sources and evidentiary standards supported by adequate levels of evidence for drug use, safety, efficacy and place in therapy. The same sources and evidentiary standards are considered when establishing Step Therapy for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- FDA product labeling
- Published peer-review clinical literature
- Approved drug compendia
- Accepted clinical practice guidelines, consensus statements, or comparable publications
- Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
- Appropriate clinical drug information from other sources as applicable
- Comparison of similar drugs in terms of safety and efficacy
- Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
- 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
- Review and approval of step therapy coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

Pharmacy Quantity Limits:

In the development of Pharmacy Quantity Limits, CVS Caremark utilizes sources and evidentiary standards supported by adequate levels of evidence for drug use, safety, efficacy and place in therapy. The same sources and evidentiary standards are considered when establishing pharmacy Quantity Limits for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- FDA product labeling
- Published peer-review clinical literature
MHPAEA Summary Form

- Approved drug compendia
- Accepted clinical practice guidelines, consensus statements, or comparable publications
- Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
- Appropriate clinical drug information from other sources as applicable
- Comparison of similar drugs in terms of safety and efficacy
- Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
- 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
- Review and approval of QLs that are outside of the FDA label and clinical appropriateness of coverage criteria for QLs by the CVS Caremark National P&T Committee

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

Pharmacy Prior Authorization:

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.

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.
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.

Pharmacy prior authorization is applied consistently across all drugs and drug classes and does not discriminate against individuals based on 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, sources or evidentiary standards, processes and development or implementation strategies used in applying the limitations to drugs used to treat medical or surgical conditions.

**Pharmacy Step Therapy:**

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 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.

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.

Pharmacy step therapy is applied consistently across all drugs and drug classes and does not discriminate against individuals based on 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, sources or evidentiary standards, processes and development or implementation strategies used in applying the limitations to drugs used to treat medical or surgical conditions.

**Pharmacy 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 drug, 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.

Pharmacy quantity limits are applied consistently across all drugs and drug classes and do not discriminate against individuals based on 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, sources or evidentiary standards, processes and development or implementation strategies used in applying the limitations to drugs used to treat medical or surgical conditions.

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

<table>
<thead>
<tr>
<th>PRIOR AUTHORIZATION (PA) ANALYSIS</th>
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<tbody>
<tr>
<td>Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021</td>
</tr>
<tr>
<td>Category</td>
</tr>
<tr>
<td>Medical / Surgical</td>
</tr>
<tr>
<td>36</td>
</tr>
<tr>
<td>Tier</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td><strong>TOTAL Drug Count by Tier</strong></td>
</tr>
<tr>
<td><strong>PA Drug Count by Tier</strong></td>
</tr>
<tr>
<td><strong>% of Total PA Drugs by Tier</strong></td>
</tr>
<tr>
<td><strong>% MED/SURG Drugs with PA</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mental Health</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Drug Count by Tier</strong></td>
<td>0</td>
<td>115</td>
<td>2</td>
<td>12</td>
<td>0</td>
<td>3</td>
<td>132</td>
</tr>
<tr>
<td><strong>PA Drug Count by Tier</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td><strong>% of Total PA Drugs by Tier</strong></td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>50.0%</td>
<td>0.0%</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td><strong>% MH Drugs with PA</strong></td>
<td>0.0%</td>
<td>0.0%</td>
<td>25.0%</td>
<td>0.0%</td>
<td>100.0%</td>
<td>4.5%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Use Disorder</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Drug Count by Tier</strong></td>
<td>4</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td><strong>PA Drug Count by Tier</strong></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MH/SUD DRUG CLASSES WITH PA</strong></td>
</tr>
<tr>
<td>ANTIANXIETY</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
</tr>
<tr>
<td>Emsam</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Prior Authorization Factors</th>
<th>Count of Drugs with PA</th>
<th>Count of Drugs with PA</th>
<th>Percent of Drugs with PA</th>
</tr>
</thead>
</table>
| ANTIPSYCHOTIC S | > 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%                       |
| Latuda Nuplazid caps, tabs | > 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%                      |
| HYPNOTICS      | > 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 | 21                      | 0                       | 0%                       |
| 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 | 13                      | 1                       | 8%                       |
| ADHD           | > Use in appropriate patient populations  
                   > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents  
                   > Requirement for additional treatment supportive therapies |  |  |  |
| 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 |  |  |  |

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:

<table>
<thead>
<tr>
<th>MED/SURG DRUG CLASSES WITH PA</th>
<th>Prior Authorization Factors</th>
<th>TOTA L Drug Count</th>
<th>Count of Drugs with PA</th>
<th>Percent of Drugs with PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

39
## MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
<th>Compliance Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANTIVIRALS - HEPATITIS C</strong></td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>23 / 18 / 78%</td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
</tr>
<tr>
<td><strong>ANTINEOPLASTIC &amp; ADJUNCTIVE THERAPIES</strong></td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>136 / 109 / 80%</td>
</tr>
<tr>
<td></td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
</tr>
<tr>
<td><strong>OSTEOPOROSIS AGENTS</strong></td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>13 / 6 / 46%</td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
</tr>
<tr>
<td><strong>GROWTH HORMONE</strong></td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>15 / 15 / 100%</td>
</tr>
<tr>
<td></td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td></td>
</tr>
<tr>
<td><strong>GI - PANCREATIC ENZYMES</strong></td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>4 / 4 / 100%</td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
</tr>
<tr>
<td>Drug Class</td>
<td>Description</td>
<td>Compliance Rate</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
<td>----------------</td>
</tr>
</tbody>
</table>
| ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXANTS | > 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% |
| 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical / Surgical</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td></td>
<td>72</td>
<td>985</td>
<td>137</td>
<td>157</td>
<td>199</td>
<td>196</td>
<td>1,746</td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td></td>
<td>0</td>
<td>11</td>
<td>14</td>
<td>23</td>
<td>0</td>
<td>0</td>
<td>48</td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td></td>
<td>0.0%</td>
<td>22.9%</td>
<td>29.2%</td>
<td>47.9%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>% MED/SURG Drugs with ST</td>
<td></td>
<td>0.0%</td>
<td>1.1%</td>
<td>10.2%</td>
<td>14.6%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>2.7%</td>
</tr>
<tr>
<td><strong>Mental Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td></td>
<td>0</td>
<td>115</td>
<td>2</td>
<td>12</td>
<td>0</td>
<td>3</td>
<td>132</td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td></td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td></td>
<td>0.0%</td>
<td>11.1%</td>
<td>0.0%</td>
<td>88.9%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>% MH Drugs with ST</td>
<td></td>
<td>0.0%</td>
<td>0.9%</td>
<td>0.0%</td>
<td>66.7%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>6.8%</td>
</tr>
<tr>
<td><strong>Substance Use Disorder</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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:
MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Products</th>
<th>Step Therapy Factors</th>
<th>TOTAL Count</th>
<th>Percent of</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIANXIETY</td>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
<td>Desvenlafaxine ER Fetzima cap/Pack Trintellix Viibryd tab/Pack</td>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td>47</td>
<td>6</td>
</tr>
<tr>
<td>ANTIPSYCHOTICS</td>
<td>Rexulti</td>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td>35</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPNOTICS</td>
<td></td>
<td></td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>ADHD</td>
<td>Vyvanse caps, chew</td>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td>21</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUD</td>
<td></td>
<td></td>
<td>13</td>
<td>0</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>State of MD-AETNA - Small Group Exchange Closed ST Formulary - 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>MED/SURG DRUG CLASSES WITH ST</td>
</tr>
<tr>
<td>Step Therapy Factors</td>
</tr>
<tr>
<td>TOTA L</td>
</tr>
</tbody>
</table>

44
<table>
<thead>
<tr>
<th>Category</th>
<th>Drug Count</th>
<th>Drugs with ST</th>
<th>Drugs with ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIDIABETICS</td>
<td>56</td>
<td>24</td>
<td>43%</td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSTEOPOROSIS AGENTS</td>
<td>13</td>
<td>1</td>
<td>8%</td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NASAL AGENTS</td>
<td>8</td>
<td>1</td>
<td>13%</td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>URINARY ANTISPASMODICS</td>
<td>12</td>
<td>1</td>
<td>8%</td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GU - BPH</td>
<td>7</td>
<td>1</td>
<td>14%</td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIBROMYALGIA AGENTS</td>
<td>2</td>
<td>2</td>
<td>100%</td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### MHPAEA Summary Form

| 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical / Surgical</td>
<td></td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>72</td>
</tr>
<tr>
<td>QL Drug Count by Tier</td>
<td>55</td>
</tr>
<tr>
<td>% of Total QL Drugs by Tier</td>
<td>7.6%</td>
</tr>
</tbody>
</table>
### MHPAEA Summary Form

#### % MED/SURG Drugs with QL

<table>
<thead>
<tr>
<th>Tier</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>115</td>
<td>2</td>
<td>12</td>
<td>0</td>
<td>3</td>
<td>132</td>
</tr>
<tr>
<td>1</td>
<td>37</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>46</td>
</tr>
</tbody>
</table>

#### Mental Health

<table>
<thead>
<tr>
<th>Tier</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>115</td>
<td>2</td>
<td>12</td>
<td>0</td>
<td>3</td>
<td>132</td>
</tr>
<tr>
<td>1</td>
<td>37</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>46</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% of Total QL Drugs by Tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% MH Drugs with QL</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0%</td>
</tr>
</tbody>
</table>

#### Substance Use Disorder

<table>
<thead>
<tr>
<th>Tier</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% of Total QL Drugs by Tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>57.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% SUD Drugs with QL</th>
</tr>
</thead>
<tbody>
<tr>
<td>100.0%</td>
</tr>
</tbody>
</table>

* 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:

<table>
<thead>
<tr>
<th>State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MH/SUD DRUG CLASSES WITH QL</strong></td>
</tr>
<tr>
<td><strong>ANTIANXIETY</strong> Alprazolam tabs, Intensol oral conc, oral susp, ODT Chlordiazepoxide Clorazepate Diazepam oral conc, oral soln, tabs Lorazepam oral conc, tabs Oxazepam</td>
</tr>
<tr>
<td>Category</td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
</tr>
<tr>
<td>ANTIPSYCHOTICS</td>
</tr>
<tr>
<td>HYPNOTICS</td>
</tr>
<tr>
<td>ADHD</td>
</tr>
</tbody>
</table>
MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Quantity Limit Factors</th>
<th>Count of Drugs with QL</th>
<th>Percent of Drugs with QL</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUD</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) &lt;br&gt; &gt; Promote appropriate dosing, including strength/frequency (PT SAFETY) &lt;br&gt; &gt; Prevent overutilization (PT SAFETY) &lt;br&gt; &gt; Possible abuse or misuse by the patient (PT SAFETY) &lt;br&gt; &gt; Prevent overutilization (COST-EFFECTIVENESS) &lt;br&gt; &gt; Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) &lt;br&gt; &gt; Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) &lt;br&gt; &gt; Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)</td>
<td>13</td>
<td>7</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>MED/SURG DRUG CLASSES WITH QL</th>
<th>Quantity Limit Factors</th>
<th>TOTAL Drug Count</th>
<th>Count of Drugs with QL</th>
<th>Percent of Drugs with QL</th>
</tr>
</thead>
</table>

50
<table>
<thead>
<tr>
<th>Category</th>
<th>Notes</th>
<th>60</th>
<th>56</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIVIRALS - HIV</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>60</td>
<td>60</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANTIVIRALS - HEPATITIS C</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>23</td>
<td>23</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTRACEPTIVES</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>55</td>
<td>55</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GROWTH HORMONE</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>15</td>
<td>15</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NASAL AGENTS</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>8</td>
<td>7</td>
<td>88%</td>
</tr>
<tr>
<td></td>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGENTS/FORMATS</td>
<td>COMMENTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>----------</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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) |
| 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)  |
| MULTIPLE SCLEROSIS AGENTS | > Promote appropriate dosing, including strength/frequency (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY)  |
| ANALGESICS - OPPIOD | > 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) |
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Points Potential</th>
<th>Points Cost</th>
<th>Percent Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MIGRAINE AGENTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)</td>
<td>23</td>
<td>21</td>
<td>91%</td>
</tr>
<tr>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DERM - POST-HERPETIC NEURALGIA</strong></td>
<td>7</td>
<td>6</td>
<td>86%</td>
</tr>
<tr>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>NQTL’s Applicable to Med/Surg Benefits in Prescription Classification</th>
<th>NQTL’s Applicable to MH/SUD Benefits in Prescription Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formulary Tiering and Design:</strong></td>
<td><strong>Formulary Tiering and Design:</strong></td>
</tr>
<tr>
<td>The tiers on a formulary determine the amount that the member pays for coverage of a prescription. The formulary tiers are based on whether the drug is formulary-eligible, included as covered on the formulary, available as a generic or a brand product, and whether the brand or generic drug product is considered preferred or non-preferred.</td>
<td>See the NQTL’s Applicable to Med/Surg Benefits response as there are no non-comparable inconsistencies or differences in the application, as written and in operation, of the Formulary Tiering and Design NQTL practices between medical/surgical and MH/SUD.</td>
</tr>
<tr>
<td><strong>Specialty Drug designation:</strong></td>
<td><strong>Specialty Drug designation:</strong></td>
</tr>
<tr>
<td>Specialty drug designation is applied to drugs or drug classes that are typically higher-cost drugs that require special handling, special storage, or close clinical monitoring of the member. Due to the special handling of the drug or the drug’s limited distribution, the prescription may need to be dispensed from a Specialty Pharmacy. The applicable copay for a specialty drug would apply.</td>
<td>See the NQTL’s Applicable to Med/Surg Benefits response as there are no non-comparable inconsistencies or differences in the application, as written and in operation, of the Specialty Drug designation NQTL practices between medical/surgical and MH/SUD.</td>
</tr>
</tbody>
</table>

   Formulary tiering and design and specialty drug classification is applicable to all medical/surgical benefits or all MH/SUD pharmacy prescription benefits.

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

   **Formulary Tiering and Design:**
   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:
   - Brand or generic status of the drug
   - Impact of generic drugs or drugs designated to become available over-the-counter
MHPAEA Summary Form

- Brand and generic pipeline
- Line of business
- Drug labeling approved by the U.S. Food and Drug Administration (FDA)
- Availability of therapeutic alternatives
- Utilization trends
- Plan sponsor cost
- Applicable manufacturer agreement
- Potential impact on members

**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:

- Pharmaceuticals, biotech, or biological drugs that are dispensed from a specialty pharmacy
- Used in the management of chronic, complex, rare, or genetic diseases
- Route of administration may be injectable, infused, inhaled, oral
- May require unique handling, distribution and/or administration
- Require clinical management to optimize safety and adherence
- May have an FDA-mandated risk evaluation and mitigation strategies (REMS) drug safety programs or Black Box Warning
- Monthly prescription costs typically greater than $600

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

**Formulary Tiering and Design:**
The same sources and evidentiary standards are considered when establishing formulary tier designation for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- FDA product labeling
- Recognized drug compendia
- Consensus documents and nationally sanctioned guidelines
- Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies
- Evidence-based reviews of peer-reviewed medical literature and relevant clinical information
MHPAEA Summary Form

- Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references
- Appropriate clinical drug information from other sources as applicable
- Input from physicians practicing in the relevant clinical area
- Review and approval at least annually, and updates as needed, of formulary drug list content by external clinical experts, who are physicians practicing in the relevant clinical area, as well as the CVS Caremark National Pharmacy & Therapeutics Committee (P&T Committee) members

**Specialty Drug designation:**
The same sources and evidentiary standards are considered when establishing specialty drug designation for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions:

- FDA product labeling
- Published peer-review clinical literature
- Approved drug compendia
- Accepted clinical practice guidelines, consensus statements, or comparable publications
- Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
- Appropriate clinical drug information from other sources as applicable
- Comparison of similar drugs in terms of safety and efficacy
- Appropriate clinical drug information from other sources as applicable
- Review by the Pharmacy Pharmaceutical Technology Evaluation Committee (PTEC)

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

**Formulary Tiering and Design:**

CVS Caremark works to include the most cost-effective drugs on the drug list. Drug decision making takes into account a variety of factors, such as indications, clinical evidence (scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines), adverse event profile, available dosage forms, dosing frequency, generic competition, and adherence factors. The formulary selection process includes a comparison of similar drugs in terms of safety and efficacy. In addition, drug and drug class appropriateness is taken into account when considering a drug for inclusion. The above processes are used when making formulary decisions for all drug classes including drugs used for MH/SUD and MED/SURG conditions.

Most 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. The generic and low-cost brand-name options offer similar efficacy and safety. 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. A three-tier formulary—typically with generics in the first, lowest cost tier; preferred brand-name drugs at second tier; and non-preferred brand-name drugs at the highest-cost third tier—is the option chosen by the vast majority of plan sponsors working with CVS Caremark.

• Many of our standard formularies also exclude certain products from coverage. The excluded products have alternatives available that will deliver cost savings to plan sponsors.

• Closed formularies will cover a set number of products and the others are not covered unless the claim goes through an override process.

All formularies include generic drugs, which are typically 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 provide the lowest net cost to clients within each therapeutic class while ensuring that options available on our drug lists 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.

Formulary benefit design and copay tiering are applied consistently across all drugs and drug classes and do not discriminate against individuals based on 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.

**Specialty Drug designation:**
The CVS Caremark Pharmaceutical Technology Evaluation Committee (PTEC) is an internal multidisciplinary committee comprised of representatives from various business areas including Medical Affairs, Specialty Product Safety, Professional Practice and others. 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 Comprehensive Drug List addition and removal decisions are made without regard to whether the drugs are used to treat MH/SUD conditions or MED/SURG conditions.

Specialty drug designation is applied consistently across all drugs and drug classes and does not discriminate against individuals based on 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 disorder are comparable to, and are applied no more stringently than the coverage factors, sources or evidentiary standards, processes and development or implementation strategies used in applying the limitations to drugs used to treat medical or surgical conditions.

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.

**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**

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical / Surgical</td>
<td>Medical / Surgical Tier 0 Tier 1 Tier 2 Tier 3 Tier 4 Tier 5 Total Drugs % Preferred**</td>
</tr>
</tbody>
</table>

Plan: State of MD-AETNA - Small Group Exchange Closed 5T Formulary - 2021
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Count by Tier</th>
<th>72</th>
<th>985</th>
<th>137</th>
<th>157</th>
<th>199</th>
<th>196</th>
<th>1,746</th>
<th><strong>79.8%</strong></th>
</tr>
</thead>
</table>

| % of Drug Count per Tier          | 4.1% | 56.4% | 7.8% | 9.0% | 11.4% | 11.2% |       |

### Mental Health

<table>
<thead>
<tr>
<th>Mental Health</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
<th>% Preferred**</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Drug Count by Tier</th>
<th>0</th>
<th>115</th>
<th>2</th>
<th>12</th>
<th>0</th>
<th>3</th>
<th>132</th>
<th><strong>88.6%</strong></th>
</tr>
</thead>
</table>

| % of Drug Count per Tier          | 0.0% | 87.1% | 1.5% | 9.1% | 0.0% | 2.3% |

### Substance Use Disorder

<table>
<thead>
<tr>
<th>Substance Use Disorder</th>
<th>Tier 0</th>
<th>Tier 1</th>
<th>Tier 2</th>
<th>Tier 3</th>
<th>Tier 4</th>
<th>Tier 5</th>
<th>Total Drugs</th>
<th>% Preferred**</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Drug Count by Tier</th>
<th>4</th>
<th>6</th>
<th>1</th>
<th>0</th>
<th>2</th>
<th>0</th>
<th>13</th>
<th><strong>100.0%</strong></th>
</tr>
</thead>
</table>

| % 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.
MHPAEA Summary Form

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical / Surgical</td>
<td></td>
</tr>
<tr>
<td>Specialty Drug Count by Tier</td>
<td>Tier 0</td>
</tr>
<tr>
<td></td>
<td>Tier 1</td>
</tr>
<tr>
<td></td>
<td>Tier 2</td>
</tr>
<tr>
<td></td>
<td>Tier 3</td>
</tr>
<tr>
<td></td>
<td>Tier 4</td>
</tr>
<tr>
<td></td>
<td>Tier 5</td>
</tr>
<tr>
<td></td>
<td>Total Specialty Drugs</td>
</tr>
<tr>
<td></td>
<td>% Specialty</td>
</tr>
<tr>
<td>Medical / Surgical</td>
<td></td>
</tr>
<tr>
<td>Specialty Drug Count by Tier</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>191</td>
</tr>
<tr>
<td></td>
<td>194</td>
</tr>
<tr>
<td></td>
<td>469</td>
</tr>
<tr>
<td></td>
<td>26.9%</td>
</tr>
<tr>
<td>% of Specialty Drugs per Tier</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>9.6%</td>
</tr>
<tr>
<td></td>
<td>7.2%</td>
</tr>
<tr>
<td></td>
<td>1.1%</td>
</tr>
<tr>
<td></td>
<td>40.7%</td>
</tr>
<tr>
<td></td>
<td>41.4%</td>
</tr>
<tr>
<td>Mental Health</td>
<td></td>
</tr>
<tr>
<td>Specialty Drug Count by Tier</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
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<td></td>
<td>0</td>
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<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2.3%</td>
</tr>
<tr>
<td>% of Specialty</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>0.0%</td>
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<td></td>
<td>0.0%</td>
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<td>0.0%</td>
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<tr>
<td></td>
<td>100.0%</td>
</tr>
</tbody>
</table>
### 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.
8. **Case Management**

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;

   This entire 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.

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

   Not applicable

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

   Not applicable

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

   Not applicable

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.

   Not applicable
9. **Process for Assessment of New Technologies**

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;

**Covered services:** All Med/Surg and MH/SUD inpatient, outpatient, and emergency care services

**Plan language:**

**Clinical trial therapies (experimental or investigational)**

**Eligible health services** include experimental or investigational drugs, devices, treatments or procedures from a **provider** under an “approved clinical trial” only when a qualified individual who is a participant or beneficiary in the health plan, is eligible to participate according to trial protocols with respect to the treatment of cancer or other life-threatening disease or condition.

Experimental or investigational

A drug, device, procedure or treatment that we find is experimental or investigational because:

- There is not enough outcome data available from controlled clinical trials published in the peer-reviewed literature to validate its safety and effectiveness for the illness or injury involved.
- Services that are not recognized as efficacious as that term is defined in the edition of the Institute of Medicine Report on Assessing Medical Technologies that is current when the care is rendered.
- The needed approval by the FDA has not been given for marketing.
- A national medical or dental society or regulatory agency has stated in writing that it is experimental or investigational or suitable mainly for research purposes.
- It is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial. These terms have the meanings given by regulations and other official actions and publications of the FDA and Department of Health and Human Services.
- Written protocols or a written consent form used by a facility provider state that it is experimental or investigational.
- It is provided or performed in a special setting for research purposes.
Clinical trial therapies (experimental or investigational)

<table>
<thead>
<tr>
<th>Description</th>
<th>In-network coverage</th>
<th>Out-of-network coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trial therapies</td>
<td>Covered based on the type of service and where it is received</td>
<td>Covered based on the type of service and where it is received</td>
</tr>
</tbody>
</table>

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

Note: All factors are the same for medical/surgical and MH/SUD. Lack of appropriate evidence establishing the safety and effectiveness of the service.

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

The processes, strategies, and evidentiary standards used to define the factors include the following:

- There are insufficient outcomes data available from controlled clinical trials published in the peer-reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or
- Approval required by the FDA has not been granted for marketing; or
- A recognized national medical or dental society or regulatory agency has determined, in writing, that it is experimental or investigational, or for research purposes; or
- It is a type of drug, device or treatment that is the subject of a Phase I or Phase II clinical trial or the experimental or research arm of a Phase III clinical trial, using the definition of “phases” indicated in regulations and other official actions and publications of the FDA and Department of Health and Human Services; or
- The written protocol or protocols used by the treating facility, or the protocol or protocols of any other facility, informed consent form used by the treating facility or by another facility studying the same drug, device, procedure, or treatment states that it is experimental or investigational, or for research purposes.

- Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations such as:
MHPAEA Summary Form

- Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Medicare Benefit Policy Manual
- MCG guidelines
- Applied Behavior Analysis Medical Necessity Guide
- InterQual guidelines (as required by contractual provisions)
- Level of Care Assessment Tool

Review of generally accepted national quality standards, i.e.) National Committee for Quality Assurance, NCQA

These processes, strategies, and evidentiary standards: are represented in Aetna Clinical Policies and in our published Aetna Clinical Policy Bulletins (CPBs)
https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html

In determining whether a medical technology is medically necessary and established, the Clinical Policy Council will consider whether the following five criteria are met:
- Whether the medical technology has final approval from the appropriate governmental regulatory bodies
- Whether the scientific evidence permits conclusions about the effect of the medical technology on health outcomes
- Whether the medical technology improves net health outcomes
- Whether the medical technology is at least as beneficial as any established alternatives
- Whether the medical technology is more costly (taking into account all health expenses incurred in connection with the medical technology) than any equally effective established alternatives

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

Refer to Section 9C.

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.

As written:
The Aetna Clinical Policy Council ongoing evaluation of Aetna’s CPBs reveals a consistent methodology of determining the experimental/investigational status of various services. The CPBs used for various Benefit Exclusion requirements 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.

**In operation:**

Aetna monitors the application of the medical necessity NQTL as follows:

The Clinical Policy Bulletins (CPBs) evidenced-based criteria which is used in administering various benefit exclusions.

Exclusions, as detailed in our CPBs, undergo a comprehensive review process. This includes review by our Clinical Policy Council and external practicing clinicians, and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines as further detailed in the Medical Necessity NQTL analysis above.

In making this determination, the Clinical Policy Council will review and evaluate evidence in the peer-reviewed published medical literature, information from the U.S. Food and Drug Administration and other Federal public health agencies, evidence-based guidelines from national medical professional organizations, and evidence-based evaluations by consensus panels and technology evaluation bodies.

The Clinical Policy council is comprised of pharmacists and medical directors from the Medical Policy Administration (MPA) department, National Accounts department, Behavioral Health department, Clinical Pharmacy department and regional Patient Management units. The Clinical Policy council usually convenes twice monthly.

**Discretion:** Exclusion of experimental/investigational benefits will not apply with respect to services or supplies (other than drugs) received in connection with a disease; if Aetna determines that:

- The disease can be expected to cause death within one year, in the absence of effective treatment; and
- The care or treatment is effective for that disease or shows promise of being effective for that disease as demonstrated by scientific data. In making this determination, Aetna will take into account the results of a review by a panel of independent medical professionals. They will be selected by Aetna. This panel will include professionals who treat the type of disease involved.
Also, this exclusion will not apply with respect to drugs that: have been granted treatment investigational new drug (IND) or Group C treatment IND status; or are being studied at the Phase III level in a national clinical trial sponsored by the National Cancer Institute; if Aetna determines that available scientific evidence demonstrates that the drug is effective or shows promise of being effective for the disease.

With regard to Aetna’s Medical Technology Evaluation and Clinical Policy Development Process, Aetna’s Clinical Policy Bulletins (CPBs) previously referenced define our policy regarding the experimental and investigational status and medical necessity of medical technologies (e.g., medical and surgical procedures, devices, pharmaceuticals, biological products, behavioral health interventions, and the organizational and supportive systems within which such care is provided) that may be eligible for coverage under our medical plans. The CPBs are used in conjunction with the terms of the member’s benefit plan and other Aetna-recognized criteria to determine health care coverage for our members.
10. Standards for Provider Credentialing and Contracting

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;

   **Covered services:** Applies to all Med/Surg and MH/SUD benefits delivered in-network

   **Plan language:** No reference

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

   Note: All factors are the same for medical/surgical and MH/SUD
   • Applicable state law, federal law, and accreditation network adequacy requirements

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

   **Network Adequacy**
   • NCQA standards (Aetna is NCQA Health Plan Accredited)
   • Network adequacy indicators are based on NCQAs NET 1 (AVAILABILITY OF PRACTITIONERS) and NET 2 (ACCESSIBILITY OF SERVICES)
   • State specific Network Adequacy as appliable

   **Provider Admission Standards NQTL: Outpatient group and individual providers**
   • NCQA standards (Aetna is NCQA Health Plan 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 Standards NQTL: Facility and Facility-Based Practitioners**
   • NCQA standards (Aetna is NCQA Health Plan Accredited)
MHPAEA Summary Form

- 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.

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

Refer to Section 10C.

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.

As written:

**Network Adequacy**
The same 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. Aetna maintains uniform network adequacy practices that are equally applicable to MH/SUD and medical/surgical.

**Provider Admission Standards NQTL: Outpatient group and individual providers**
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.

**Provider Admission Standards NQTL: Facility and Facility-Based Practitioners**
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. Aetna maintains one set of credentialing policies that are equally applicable to MH/SUD and medical/surgical.

In operation:

**Network Adequacy**
Aetna monitors the application of this NQTL through several initiatives:

- Oversight of network adequacy reporting by the National Quality Oversight Committee NQOC.
- A qualitative and quantitative analysis by product/product line is performed using network adequacy data which includes member complaints/grievances and appeals, accessibility, availability, out of network requests, and member experience data (CAHPS or member experience survey).
- Network adequacy complaints/grievances and appeals at or in excess of .01 per thousand member months will trigger an additional review. The rate per thousand member months shall be calculated as follows: [# of complaints or appeals]/(monthly total for 12 months of membership/1000)]
- Out-Of-Network requests for and utilization services will be reported at the product line-level per thousand members. The rate per thousand members shall be calculated as follows: [# of Out-of-Network requests]/1,000 enrollees) (membership/1000).

The results of the above analysis will be reviewed in conjunction with the findings of the network availability and accessibility analyses to identify and prioritize opportunities for improvement. One improvement for non-behavioral health and one for behavioral health will be implemented.

**Provider Admission Standards NQTL: Outpatient group and individual providers and Facility and Facility-Based Practitioners**

Aetna monitors the application this NQTL through several initiatives:

- Mental Health Parity Task Force: Multi-disciplinary team that meets bi-weekly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.
- Credentialing rate and turnaround time reports
11. **Exclusions for Failure to Complete a Course of Treatment**

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;

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

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

   Not applicable

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

   Not applicable

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

   Not applicable

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.

   Not applicable
12. Restrictions that Limit Duration or Scope of Benefits for Services

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;

The plan does not impose any geographic location restrictions on covered services. As such this section is not applicable.

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

Not applicable

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

Not applicable

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

Not applicable

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.

Not applicable
13. Restrictions for Provider Specialty

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;

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.

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

Not applicable

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

Not applicable

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

Not applicable

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.

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;

**Participating Provider and Facility Reimbursement**

**Covered services:** Applies to all Med/Surg and MH/SUD benefits delivered in-network

**Plan language:**

**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.

*For prescription drug services from a network pharmacy:*  
The amount we established for each prescription drug obtained from a network pharmacy under this plan. This **negotiated charge** may reflect amounts we agreed to pay directly to the network pharmacy or to a third party vendor for the prescription drug, and may include a rebate, an additional service or risk charge set by us.

We may receive or pay additional amounts from or to third parties under price guarantees. These amounts may not change the **negotiated charge** under this plan.

**Non-Participating Provider and Facility Reimbursement**  
**Covered services:** Applies to all Med/Surg and MH/SUD benefits delivered out-of-network  
**Plan language:**  
**Recognized charge**  
The amount of an out-of-network provider’s charge that is eligible for coverage. You are responsible for all amounts above the recognized charge. The **recognized charge** may be less than the provider’s full charge. The **recognized charge** will never be less than the negotiated charge.

The **recognized charge** depends on the geographic area where you receive the service or supply. The table below shows the method for calculating the **recognized charge** for specific services or supplies:

<table>
<thead>
<tr>
<th>Service or supply</th>
<th>Recognized charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional services and other services or supplies not mentioned below</td>
<td>The <em>Aetna</em> out-of-network rate (AONR)</td>
</tr>
<tr>
<td>Services of hospitals and other facilities</td>
<td>Other than those hospital services regulated by the HSCRC, is the lesser of what the provider bills and 150-250% of the Medicare allowable rate.</td>
</tr>
</tbody>
</table>
MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Prescription drugs</th>
<th>110% of the average wholesale price (AWP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental expenses</td>
<td>80% of the prevailing charge rate</td>
</tr>
</tbody>
</table>

**Important note:** if the **provider** bills less than the amount calculated using the method above, the **recognized charge** is what the **provider** bills.

**Recognized charge** does not apply to involuntary services.

**Special terms used**

- **Aetna out-of-network rates (AONR)** are our standard rates used to begin contract talks with **providers** in a specific geographic area.

- Average wholesale price (AWP) is the current average wholesale price of a **prescription drug** listed in the Facts and Comparisons, Medi-span weekly price updates (or any other similar publication chosen by **Aetna**).

- Geographic area is normally based on the first three digits of the U.S. Postal Service zip codes. If we determine we need more data for a particular service or supply, we may base rates on a wider geographic area such as an entire state.

- Involuntary services are services or supplies that are one of the following:
  - Performed at a **network** facility by an **out-of-network provider**, unless that **out-of-network provider** is an assistant surgeon for your **surgery**
  - Not available from a **network provider**
  - **Emergency services**

We will calculate your cost share for involuntary services in the same way as we would if you received the services from a **network provider**.
When the recognized charge is based on a percentage of the Medicare allowed rate, it is not affected by adjustments or incentives given to providers under Medicare programs.

- Prevailing charge rate is the percentile value reported in a database prepared by FAIR Health, a nonprofit company. FAIR Health changes these rates periodically. We update our systems with these changes within 180 days after receiving them from FAIR Health. If the Fair Health database becomes unavailable, we have the right to substitute a different database that we believe is comparable.

Our reimbursement policies

We reserve the right to apply our reimbursement policies to all out-of-network services including involuntary services. Our reimbursement policies may affect the recognized charge. These policies consider:

- The duration and complexity of a service
- When multiple procedures are billed at the same time, whether additional overhead is required
- Whether an assistant surgeon is necessary for the service
- If follow up care is included
- Whether other characteristics modify or make a particular service unique
- When a charge includes more than one claim line, whether any services described by a claim line are part of, or related to, the primary service provided
- The educational level, licensure or length of training of the provider

Our reimbursement policies are based on our review of:

- The Centers for Medicare and Medicaid Services’ (CMS) National Correct Coding Initiative (NCCI) and other external materials that say what billing and coding practices are and are not appropriate
- Generally accepted standards of medical and dental practice and
- The views of physicians and dentists practicing in the relevant clinical areas

We use commercial software to administer some of these policies. The policies may be different for professional services and facility
Get the most value out of your benefits:
We have online tools to help you decide whether to get care and, if so, where. Use the “Estimate the Cost of Care” or “Payment Estimator” tool on Aetna website. Aetna’s member website at www.aetna.com may contain additional information that can help you determine the cost of a service or supply.

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

**Participating Provider Reimbursement**
Note: All factors are the same for medical/surgical and MH/SUD
- Reimbursement rate indices (e.g. Medicare reimbursement rates)
- Market dynamics (e.g. supply and demand)
- Provider type (e.g. MD, NP)
- Service type (e.g. counseling, initial assessment)
- Performance based programs

**Participating Facility Reimbursement**
Note: All factors are the same for medical/surgical and MH/SUD
- Market dynamics (e.g. supply and demand, volume with Aetna)
- Performance based programs
- Scope and complexity of services provided
- Aetna membership presence within region

**Non-Participating Provider Reimbursement**
Note: All factors are the same for medical/surgical and MH/SUD
- Reasonable and Customary rates benchmarked from reimbursement rate indices

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

• Reasonable and Customary rates benchmarked from reimbursement rate indices

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

**Participating Provider Reimbursement**

- Standard fee schedules:
  - Benchmarked from Medicare reimbursement rates
  - Developed for each market based on market analysis
- Final negotiated rate – either standard rates or a negotiated fee schedule

**Participating Facility Reimbursement**

- Benchmarked from Medicare Inpatient Psychiatric Facility Prospective Payment System
- Market analysis
- Negotiated reimbursement models (e.g. per diem versus DRG)
- Final rate negotiated from standard target ranges

**Non-Participating Provider Reimbursement**

- Rate hierarchy (i.e. a preset algorithm that generates the rate that will be paid based on certain factors)
- Market analysis when rate hierarchy is not applicable
- Final negotiated rate

**Non-Participating Facility Reimbursement**

- Rate hierarchy (i.e. a preset algorithm that generates the rate that will be paid based on certain factors)
- Market analysis when rate hierarchy is not applicable
- Final rate negotiated as part of the rate hierarchy process

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

Refer to Section 14C.
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.

As written:

**Participating Provider Reimbursement**
MH/SUD standard fee schedule rates can be higher but are not lower than medical rates for the same codes that can be used by BH and medical/surgical providers.
The process to determine provider network reimbursement between Medical/Surgical and MH/SUD is as follows:

Medical informs Behavioral Health that they are adjusting the standard rates for a given market. Medical supplies the new medical rates for the codes shared with the behavioral health fee schedule.

BH will provide rates to medical for MH/SUD services in the BH Network. Behavioral Health will compare the rates to the medical rates. If the medical rate is the higher rate, Behavioral Health will adopt the medical rate. Behavioral Health will cascade the rate down to the lower level providers using the following CMS guidelines and commensurate with level of training:

*MD’s (MH/SUD and medical/surgical) & Clinical Psychologists receive 100% of the rate.

Nurse Practitioners, Physician Assistants and Certified Nurse Specialist (MH/SUD and medical/surgical) receives 85% of the new rate.**

Master Level Clinical Social Workers providers receive 75% of the new rate.***

** If the existing MH/SUD rate is higher than 85% of the new rate, the already existing rate stays in place

*** If the existing MH/SUD rate is higher than the 75% of the new rate, the already existing rate stays in place

The rates are effective at the same time as the new medical rates. MH/SUD rates can be updated in addition to the rate updates triggered by the Medical rate updates.

Aetna maintains uniform reimbursement practices that are equally applicable to MH/SUD and medical/surgical.

**Participating Facility Reimbursement**
Prior to negotiating such rates with a particular facility provider, Aetna has developed a set of standard target rates based on the average rates paid for similar services in a particular market. These target rates are updated annually based on average rate increases. Rates are then negotiated on the basis of these target ranges, rather than a set fee schedule. In general, the majority of rates negotiated with freestanding facilities fall within a targeted rate range differential to the average as a whole. Aetna maintains uniform reimbursement practices that are equally applicable to MH/SUD and medical/surgical.

**Non-Participating Provider Reimbursement**
Aetna compensates nonparticipating providers based on member’s plan and benefit level subject to the lesser of either the billed charges or the allowable amount determined by a standard rate hierarchy that is the same for both MH/SUD and M/S.

First tier of hierarchy includes availability of a National Advantage Program (NAP) rate, second tier includes any ad hoc negotiated rate, third tier includes payment of the plan rate (which would be within the filed and approved range).

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**In operation:**

**Participating Provider Reimbursement**
Aetna monitors the application of this NQTL through several initiatives:

- Mental Health Parity Task Force: Multi-disciplinary team that meets bi-weekly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.

- Rates are updated, and new schedules are completed and reviewed by a different person to make sure they are accurate. The rates are reviewed on both Medical and BH by members of the enterprise senior network team as well as by members of the senior regional market team.
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