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:

Medically necessary, medical necessity
The medical necessity requirements are in the Glossary section, where we define “medically necessary, medical necessity.” That is where we also explain what our medical directors or a physician they assign consider when determining if a service is medically necessary.

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

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

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

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

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
MHPAEA Summary Form

- 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](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.
**MHPAEA Summary Form**

**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](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.

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](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 [, referral] and precertification requirements

[Note: The second bullet will print when the policyholder’s plan doesn’t require referrals. The third bullet will print when the policyholder’s plan requires PCP selection and PCP referral for specialist care.]

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

- The service is medically necessary
- [For in-network benefits, you get the service from a network provider]
- [For in-network benefits, you get your care from:
  - Your PCP
  - Another network provider after you get a referral from your PCP. Referrals are not required for OB, GYN and OB/GYN network providers.]
- You or your provider precertifies the service when required

Precertification

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

[Note: This provision will not print for non-network plans.]

In-network

Your network physician or PCP is responsible for obtaining any necessary precertification before you get the care. Network providers cannot bill you if they fail to ask us for precertification. But if your physician or PCP requests precertification and we deny it, and you still choose to get the care, you will have to pay for it yourself.

[Note: This provision prints for PPO.]

Out-of-network

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

- Your benefits may be reduced, or the plan may not pay. See your schedule of benefits for details.
You will be responsible for the unpaid bills.

Your additional out-of-pocket expenses will not count toward your deductible or maximum out-of-pocket limit.

[Note: This provision will print for an Aetna international plan.]

Outside the U.S.
You are not required to get precertification for services obtained outside the U.S.

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

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

<table>
<thead>
<tr>
<th>Type of care</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-emergency admission</td>
<td>Call at least 7 days before the date you are scheduled to be admitted</td>
</tr>
<tr>
<td>Emergency admission</td>
<td>Call within 48 hours or as soon as reasonably possible after you have been admitted</td>
</tr>
<tr>
<td>Urgent admission</td>
<td>Call before you are scheduled to be admitted</td>
</tr>
<tr>
<td>Outpatient non-emergency medical services</td>
<td>Call at least 7 days before the care is provided, or the treatment or procedure is scheduled</td>
</tr>
</tbody>
</table>

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

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

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

If you or your provider request precertification and we don’t approve coverage, we will tell you why and explain how you or your provider may request review of our decision. See the Complaints, claim decisions and appeal procedures section.
[Note: This item prints for all plans except EPO. Any of the inpatient or outpatient services within the brackets will print if the policyholder's plan requires precertification for it.]

[13.] [The list of services that need precertification under the Precertification provision in the How your plan works, Medical necessity[, referral] and precertification requirements section is revised as follows:

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>Gene-based, cellular and other innovative therapies (GCIT)</td>
<td>Applied behavior analysis</td>
</tr>
<tr>
<td>Obesity (bariatric) surgery</td>
<td>Complex imaging</td>
</tr>
<tr>
<td>Stays in a hospice facility</td>
<td>Comprehensive infertility services and ART services</td>
</tr>
<tr>
<td>Stays in a hospital</td>
<td>Cosmetic and reconstructive surgery</td>
</tr>
<tr>
<td>Stays in a rehabilitation facility</td>
<td>Emergency transportation by airplane</td>
</tr>
<tr>
<td>Stays in a residential treatment facility for treatment of mental health disorders and substance related disorders</td>
<td>Gene-based, cellular and other innovative therapies (GCIT)</td>
</tr>
<tr>
<td>Stays in a skilled nursing facility</td>
<td>Injectables, (immunoglobulins, growth hormones, multiple sclerosis medications, osteoporosis medications, Botox, hepatitis C medications)</td>
</tr>
<tr>
<td></td>
<td>Kidney dialysis</td>
</tr>
<tr>
<td></td>
<td>Outpatient back surgery not performed in a physician's office</td>
</tr>
<tr>
<td></td>
<td>Partial hospitalization treatment – mental health disorder and substance related disorders treatment diagnoses</td>
</tr>
<tr>
<td></td>
<td>Private duty nursing services</td>
</tr>
<tr>
<td></td>
<td>Sleep studies</td>
</tr>
<tr>
<td></td>
<td>Transcranial magnetic stimulation (TMS)</td>
</tr>
<tr>
<td></td>
<td>Wrist surgery</td>
</tr>
<tr>
<td></td>
<td>Knee surgery]</td>
</tr>
</tbody>
</table>

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].

Certain **prescription** drugs are covered under the medical plan when they are given to you by your doctor or health care facility. The following **precertification** information applies to these **prescription** drugs:

[Note: The below four paragraphs print when the policyholder’s plan requires drug precertification.]

For certain drugs, your **provider** needs to get approval from us before we will cover the drug. The requirement for getting approval in advance guides appropriate use of certain drugs and makes sure they are **medically necessary**.

[Note: This will print when the policyholder’s plan requires step therapy.]

**Step therapy** is a type of **precertification** where we require you to first try certain drugs to treat your medical condition before we will cover another drug for that condition.

We will waive **step therapy** if any of the following conditions is met:

- The **step therapy** drug is not approved by the FDA for your medical condition
- Your **prescriber** provides supporting medical information showing that a covered **prescription** drug
  - Was ordered for you within the past 180 days, and
  - In their professional judgement, was effective in treating your disease or condition
- A **prescription** drug approved by the FDA if:
  - The drug is used to treat your stage four advanced metastatic cancer; and
  - Use of the drug is:
    - Consistent with the FDA approved indication or The National Comprehensive Cancer Network Drugs & Biologics Compendium Indication for the treatment of your cancer, and
    - Supported by peer-reviewed medical literature

[Note: Precertification, step therapy, or both will print based on the policyholder’s plan.]

Contact us or go online to get the most up-to-date **precertification** requirements [and] [list of step therapy drugs].

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

**Step therapy**
A form of precertification under which certain prescription drugs are excluded from coverage, unless a first-line therapy drug is used first by you. The list of step therapy drugs is subject to change by us or an affiliate. An updated copy of the list of drugs subject to step therapy is available upon request or on our website at [https://www.aetna.com/individuals-families/find-a-medication.html].

[Precertification covered services reduction
This only applies to out-of-network covered services:
Your certificate contains a complete description of the precertification process. You will find details in the Medical necessity, referral and precertification section.
If precertification for covered services isn’t completed, when required, it results in the following benefit reduction:
* [A [0%-50%] coinsurance reduction applied separately to the benefit provided for each covered service
* A benefit reduction of [0%-50%] up to a maximum of [$100-$500] for each type of covered service
* Covered services reduced by the lesser of [0%-50%] of the benefit that would have been payable and [$100-$500]
* A [$100-$500] benefit reduction applied separately to each type of covered service
* The service is not covered]
You may have to pay an additional portion of the allowable amount because you didn’t get precertification. This portion is not a covered service and doesn’t apply to your deductible or maximum out-of-pocket limit, if you have one.]

**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:**

**Habilitation therapy services**

Habilitation therapy services are services and devices, including occupational therapy, physical therapy and speech therapy, 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). You are covered up to at least age 20. The services must follow a specific treatment plan, ordered by your **physician**. The services must be performed by a:

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

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

Covered services include:

- Physical therapy
- Occupational therapy
- Speech therapy (speech function is the ability to express thoughts, speak words and form sentences)
The following are not covered services:

- Services provided in a training setting or to teach sign language
- Vocational rehabilitation or employment counseling

[Private duty nursing - outpatient]

Covered services include private duty nursing care, ordered by a physician and provided by an R.N. or L.P.N. when:

- You are homebound
- Your physician orders services as part of a written treatment plan
- Services take the place of a hospital or skilled nursing facility stay
- Your condition is serious, unstable, and requires continuous skilled 1-on-1 nursing care
- Periodic skilled nursing visits are not adequate

The following are not covered services:

- Inpatient private duty nursing care
- Care provided outside the home
- Maintenance or custodial care
- Care for your convenience or the convenience of the family caregiver

Short-term cardiac and pulmonary rehabilitation services

Cardiac rehabilitation

Covered services include cardiac rehabilitation services you receive at a hospital, skilled nursing facility or physician's office, but only if those services are part of a treatment plan determined by your risk level and ordered by your physician.

Pulmonary rehabilitation

Covered services include pulmonary rehabilitation services as part of your inpatient hospital stay if they are part of a treatment plan ordered by your physician. A course of outpatient pulmonary rehabilitation may also be covered if it is performed at a hospital, skilled
nursing facility or physician’s office, is used to treat reversible pulmonary disease states, and is part of a treatment plan ordered by your physician.

[Note: This item prints when the policyholder’s plan changes the short-term rehab benefit.]

[18.] [The Short-term rehabilitation services provision in the Coverage and exclusions section is revised as follows:

**Short-term rehabilitation services**
Short-term rehabilitation services help you restore or develop skills and functioning for daily living. The services must follow a specific treatment plan, ordered by your physician. 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

[Note: Any of the bulleted services will print when the policyholder’s plan covers it.]

**Covered services** include:

- [Spinal manipulation to correct a muscular or skeletal problem. Your provider must establish or approve a treatment plan that details the treatment and specifies frequency and duration.
- An initial evaluation for developmental disabilities and, if diagnosed, outpatient physical, occupational and speech therapies for treatment.]

**Cognitive rehabilitation, physical, occupational, and speech therapy**

**Covered 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, but only if it is expected to do one of the following:
  - Significantly improve, develop, or restore physical functions you lost as a result of an acute illness, injury, or surgical procedure
  - Help you relearn skills so you can significantly improve your ability to perform the activities of daily living on your own
Speech therapy, but only if it is expected to do one of the following:
- Significantly improve or restore lost speech function or correct a speech impairment resulting from an acute illness, injury, or surgical procedure
- Improve delays in speech function development caused by a gross anatomical defect present at birth (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

[Note: Print when the policyholder’s plan includes this limitation.]

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.

The following are not covered services:
- Services provided in an educational or training setting or to teach sign language
- Vocational rehabilitation or employment counseling

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:
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- 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

- 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
- 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
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- 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:
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
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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:
• 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
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- 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
- 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

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
A concurrent care claim extension occurs when you need us to approve more services than we already have approved. Examples are extending a hospital stay or adding a number of visits to a provider.

For an emergency or urgent request you must let us know you need this extension 24 hours before the original approval ends. You will receive a decision as soon as possible but no later than 24 hours. For all other requests you must let us know you need an extension 1 working day before the original approval ends.

Concurrent care claim reduction or termination
A concurrent care claim reduction or termination occurs when we decide to reduce or stop payment for an already approved course of treatment. We will notify you of such a determination. You will have enough time to file an appeal. Your coverage for the service or supply will continue until you receive a final appeal decision from us or an external review organization if the situation is eligible for external review.

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.

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>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>Pharmacy Prior Authorization:</strong></td>
<td><strong>Pharmacy Prior Authorization:</strong></td>
</tr>
<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>
<tr>
<td><strong>Pharmacy Step Therapy (ST):</strong></td>
<td><strong>Pharmacy Step Therapy:</strong></td>
</tr>
<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>
<tr>
<td><strong>Pharmacy Quantity Limits (QL):</strong></td>
<td><strong>Pharmacy Quantity Limits:</strong></td>
</tr>
<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
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- 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
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- 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.
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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.

**Advanced Control Formulary 2021 - Aetna**

**Pharmacy Prior Authorization (PA): Advanced Control Formulary 2021**

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<tr>
<th>PRIOR AUTHORIZATION (PA) ANALYSIS</th>
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</thead>
<tbody>
<tr>
<td>Plan: State of MD - AETNA - Advanced Control Formulary - 2021</td>
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<td>Category</td>
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<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>966</td>
<td>206</td>
<td>794</td>
<td>219</td>
<td>188</td>
<td>2,373</td>
</tr>
<tr>
<td><strong>PA Drug Count by Tier</strong></td>
<td>75</td>
<td>25</td>
<td>350</td>
<td>216</td>
<td>174</td>
<td>840</td>
</tr>
<tr>
<td>% of Total PA Drugs by Tier</td>
<td>8.9%</td>
<td>3.0%</td>
<td>41.7%</td>
<td>25.7%</td>
<td>20.7%</td>
<td></td>
</tr>
<tr>
<td>% MED/SURG Drugs with PA</td>
<td>7.8%</td>
<td>12.1%</td>
<td>44.1%</td>
<td>98.6%</td>
<td>92.6%</td>
<td><strong>35.4%</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mental Health</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>119</td>
<td>10</td>
<td>38</td>
<td>0</td>
<td>6</td>
<td>173</td>
</tr>
<tr>
<td><strong>PA Drug Count by Tier</strong></td>
<td>0</td>
<td>2</td>
<td>9</td>
<td>0</td>
<td>6</td>
<td>17</td>
</tr>
<tr>
<td>% of Total PA Drugs by Tier</td>
<td>0.0%</td>
<td>11.8%</td>
<td>52.9%</td>
<td>0.0%</td>
<td>35.3%</td>
<td></td>
</tr>
<tr>
<td>% MH Drugs with PA</td>
<td>0.0%</td>
<td>20.0%</td>
<td>23.7%</td>
<td>0.0%</td>
<td>100.0%</td>
<td><strong>9.8%</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Use Disorder</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>
</table>
Comparative Analysis for pharmacy prior authorization for Advanced Control Formulary – Aetna 2021

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 drug category compared to the MED/SURG drug category, and there is no prior authorization applying to any drugs in the SUD drug category. Pharmacy prior authorization is applied to:

- 35.4% (840 out of 2,373) of the drugs in the Medical/Surgical category
- 9.8% (17 out of 173) of the drugs in the Mental Health category
- None of the drugs in the Substance Use Disorder category

The development of pharmacy prior authorization 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 pharmacy prior authorization UM programs, and a client or health plan chooses which pharmacy prior authorization programs to include in the plan offering. The development of pharmacy prior authorization is based on the factors below.

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

### State of MD-AETNA Advanced Control Formulary

<table>
<thead>
<tr>
<th>MH/SUD DRUG CLASSES WITH PA</th>
<th>Prior Authorization Factors</th>
<th>TOTA L Drug Count</th>
<th>Count of Drugs with PA</th>
<th>Percen t of Drugs with PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIANXIETY</td>
<td>&gt; Use in appropriate patient populations</td>
<td>22</td>
<td>1</td>
<td>5%</td>
</tr>
<tr>
<td>Loreev XR</td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>47</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Sertraline caps</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spravato 56mg &amp; 84mg dose</td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANTIPSYCHOTICS</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>63</td>
<td>10</td>
<td>16%</td>
</tr>
<tr>
<td>Abilify Mycite tabs</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invega Hafyera</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lybalvi</td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuplazid caps, tabs</td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rexulti</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Versacloz</td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vraylar cap/Pack</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HYPNOTICS</td>
<td>&gt; Use in appropriate patient populations</td>
<td>12</td>
<td>2</td>
<td>17%</td>
</tr>
<tr>
<td>Hetlioz caps, oral susp</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MHPAEA Summary Form

| ADHD Azstarys | > Patient safety concerns exist/Unknown long-term safety or durability  
|              | > Appropriate medication uses based on national guidelines  
|              | > Treatment based on obtaining applicable lab values or test results  
|              | > Use in appropriate patient populations | 29 | 1 | 3% |
| SUD | | 19 | 0 | 0% |

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

Comparable MED/SURG drug classes are listed below, showing the pharmacy 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>TOTAL Drug Count</th>
<th>Count of Drugs with PA</th>
<th>Percen t of Drugs with PA</th>
</tr>
</thead>
</table>
| ANTIVIRALS - HEPATITIS C | > Appropriate medication uses based on national guidelines  
| | > Use in appropriate patient populations  
<p>| | &gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents | 14 | 11 | 79% |</p>
<table>
<thead>
<tr>
<th>Category</th>
<th>Appropriate medication uses based on national guidelines</th>
<th>Treatment based on obtaining applicable lab values or test results</th>
<th>Use in appropriate patient populations</th>
<th>Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</th>
<th>153</th>
<th>116</th>
<th>76%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTINEOPLASTIC &amp; ADJUNCTIVE THERAPIES</td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td></td>
<td>16</td>
<td>8</td>
<td>50%</td>
</tr>
<tr>
<td>OSTEOPOROSIS AGENTS</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>4</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>GROWTH HORMONE</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>5</td>
<td>4</td>
<td>80%</td>
</tr>
<tr>
<td>Category</td>
<td>Appropriate medication uses</td>
<td>Patient safety concerns</td>
<td>2022</td>
<td>2021</td>
<td>Improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------</td>
<td>-------------------------</td>
<td>------</td>
<td>------</td>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MULTIPLE SCLEROSIS AGENTS</td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td></td>
<td>20</td>
<td>20</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANALGESICS - OPIOID</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td>65</td>
<td>60</td>
<td>92%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Reduce waste, unnecessary drug use, fraud or abuse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANALGESICS - ANTI-INFLAMMATORY</td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td>56</td>
<td>28</td>
<td>50%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Use in appropriate patient populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DERM - ANTIPSYORIATICS</td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>&gt; Use in appropriate patient populations</td>
<td>16</td>
<td>13</td>
<td>81%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DERM - ANTINEOPLASTICS</td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>8</td>
<td>4</td>
<td>50%</td>
<td></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>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MHPAEA Summary Form

<table>
<thead>
<tr>
<th></th>
<th>approved indications, clinical use, and guidelines documents</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DERM - IMMUNOSUPPRESSANTS</td>
<td>&gt; Appropriate medication uses based on national guidelines &gt; Use in appropriate patient populations</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

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

Step Therapy (ST) for Advanced Control Formulary – Aetna 2021

<table>
<thead>
<tr>
<th></th>
<th>Medical / Surgical</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>Total Drug Count by Tier</td>
<td>966</td>
<td>206</td>
<td>794</td>
<td>219</td>
<td>188</td>
<td></td>
<td>2,373</td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td>1</td>
<td>27</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td></td>
<td>43</td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td>2.3%</td>
<td>62.8%</td>
<td>34.9%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% MED/SURG Drugs with ST</td>
<td>0.1%</td>
<td>13.1%</td>
<td>1.9%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
<td>1.8%</td>
</tr>
<tr>
<td>Mental Health</td>
<td>Tier 1</td>
<td>Tier 2</td>
<td>Tier 3</td>
<td>Tier 4</td>
<td>Tier 5</td>
<td>Total Drugs</td>
<td></td>
</tr>
<tr>
<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>119</td>
<td>10</td>
<td>38</td>
<td>0</td>
<td>6</td>
<td>173</td>
<td></td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td>0.0%</td>
<td>16.7%</td>
<td>83.3%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% MH Drugs with ST</td>
<td>0.0%</td>
<td>10.0%</td>
<td>13.2%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>3.5%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Use Disorder</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>Total Drug Count by Tier</td>
<td>9</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>% SUD Drugs with ST</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</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 step therapy for Advanced Control Formulary – Aetna 2021

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 drug category and the MED/SURG drug category, and there is no step therapy applying to any drugs in the SUD drug category. Pharmacy step therapy is applied to:

- 1.8% (43 out of 2,373) of the drugs in the Medical/Surgical category.
- 3.5% (6 out of 173) 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 UM 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 in each drug class for this plan:

<table>
<thead>
<tr>
<th>State of MD-AETNA Advanced Control Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MH/SUD DRUG CLASSES WITH ST</strong></td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td>ANTIANXIETY</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
</tr>
<tr>
<td>Desvenlafaxine</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
## MHPAEA Summary Form

<table>
<thead>
<tr>
<th>ER</th>
<th>Trintellix</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIPSYCHOTICS</td>
<td>63</td>
<td>0</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>HYPNOTICS</td>
<td>12</td>
<td>1</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>ADHD Dyanavel XR Quillichew ER Quillivant XR</td>
<td>29</td>
<td>3</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>SUD</td>
<td>19</td>
<td>0</td>
<td>0%</td>
<td></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 in the comparable drug classes for this plan:

<table>
<thead>
<tr>
<th>MED/SURG DRUG CLASSES WITH ST</th>
<th>Step Therapy Factors</th>
<th>TOTAL Drug Count</th>
<th>Count of Drugs with ST</th>
<th>Percent of Drugs with ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>State of MD-AETNA Advanced Control Formulary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MHPAEA Summary Form</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANTIDIABETICS</strong></td>
<td></td>
<td></td>
<td></td>
<td></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>
<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>
<td></td>
</tr>
<tr>
<td>70</td>
<td>14</td>
<td>20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OSTEOPOROSIS AGENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td></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>
<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>
<td></td>
</tr>
<tr>
<td>16</td>
<td>2</td>
<td>13%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANTIHYPERTENSIVES</strong></td>
<td></td>
<td></td>
<td></td>
<td></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>
<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>
<td></td>
</tr>
<tr>
<td>57</td>
<td>1</td>
<td>2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>URINARY ANTISPASMODICS</strong></td>
<td></td>
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<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
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<td></td>
<td></td>
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</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>
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</tr>
<tr>
<td>17</td>
<td>4</td>
<td>24%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GU - BPH</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
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<tr>
<td>7</td>
<td>1</td>
<td>14%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FIBROMYALGIA AGENTS</strong></td>
<td></td>
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<td></td>
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<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
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<td></td>
</tr>
<tr>
<td>&gt; Alternatives available in the drug class (including generics) used to treat the same condition</td>
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<td></td>
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<tr>
<td>2</td>
<td>2</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MIGRAINE PRODUCTS</strong></td>
<td></td>
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</tr>
<tr>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>&gt; Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>10</td>
<td>34%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Description</th>
<th>QL Count</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>
</table>
| DERM - ANTIPSORIATICS | > 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 | 16       | 2      |        |        |        |        | 783         |

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

Quantity Limits (QL) for Advanced Control Formulary – Aetna 2021

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</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>Medical / Surgical</td>
<td>Total Drug Count by Tier</td>
<td>966</td>
<td>206</td>
<td>794</td>
<td>219</td>
<td>188</td>
<td>2,373</td>
</tr>
<tr>
<td>Medical / Surgical</td>
<td>QL Drug Count by Tier</td>
<td>219</td>
<td>62</td>
<td>121</td>
<td>209</td>
<td>172</td>
<td>783</td>
</tr>
</tbody>
</table>
## MHPAEA Summary Form

<table>
<thead>
<tr>
<th></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>Mental Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>119</td>
<td>10</td>
<td>38</td>
<td>0</td>
<td>6</td>
<td>173</td>
</tr>
<tr>
<td>QL Drug Count by Tier</td>
<td>38</td>
<td>3</td>
<td>12</td>
<td>0</td>
<td>4</td>
<td>57</td>
</tr>
<tr>
<td>% of Total QL Drugs by Tier</td>
<td>66.7%</td>
<td>5.3%</td>
<td>21.1%</td>
<td>0.0%</td>
<td>7.0%</td>
<td></td>
</tr>
<tr>
<td>% MH Drugs with QL</td>
<td>31.9%</td>
<td>30.0%</td>
<td>31.6%</td>
<td>0.0%</td>
<td>66.7%</td>
<td>32.9%</td>
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<tr>
<td><strong>Substance Use Disorder</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>9</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>QL Drug Count by Tier</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>% of Total QL Drugs by Tier</td>
<td>36.4%</td>
<td>9.1%</td>
<td>45.5%</td>
<td>0.0%</td>
<td>9.1%</td>
<td></td>
</tr>
</tbody>
</table>
Comparative Analysis for Quantity Limits for Advanced Control Formulary – Aetna 2021

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:

- 33.0% (783 out of 2,373) of the drugs in the Medical/Surgical category.
- 32.9% (57 out of 173) of the drugs in the Mental Health category.
- 57.9% (11 out of 19) 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 Advanced Control Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH/SUD DRUG CLASSES WITH QL</td>
</tr>
<tr>
<td>Quantity Limit Factors</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
## MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Category</th>
<th>Drugs</th>
<th>Potential Issues</th>
<th>with QL</th>
<th>with QL</th>
</tr>
</thead>
</table>
| **ANTIANXIETY**   | Alprazolam tabs, ER tab, Intensol oral conc, oral susp, ODT Chlordiazepoxide Clonazepam tab, ODT Clorazepate Diazepam oral conc, oral soln, tabs Lorazepam oral conc, tabs Oxazepam | > 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) | 22      | 16      | 73%     |
| **ANTIDEPRESSANTS** | Desvenlafaxine ER                                                   | > Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)  
> Promote appropriate dosing, including strength/frequency (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY) | 47      | 1       | 2%      |
| **ANTIPSYCHOTICS** | Nuplazid caps, tabs                                                 | > Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)  
> Promote appropriate dosing, including strength/frequency (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY) | 63      | 2       | 3%      |
<table>
<thead>
<tr>
<th>HYPNOTICS</th>
<th>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</th>
<th>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</th>
<th>&gt; Prevent overutilization (PT SAFETY)</th>
<th>&gt; Possible abuse or misuse by the patient (PT SAFETY)</th>
<th>12</th>
<th>11</th>
<th>92%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estazolam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eszopiclone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Flurazepam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hetlloz caps, oral susp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramelteon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temazepam</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Triazolam</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Zaleplon</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Zolpidem tab, ER tab</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

| ADHD | > Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) | > Promote appropriate dosing, including strength/frequency (PT SAFETY) | > Prevent overutilization (PT SAFETY) | > Possible abuse or misuse by the patient (PT SAFETY) | > Prevent overutilization (COST-EFFECTIVENESS) | > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) | > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) | > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE) | 29 | 27 | 93% |
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>SUD</th>
<th>Quantity Limit Factors</th>
<th>Count</th>
<th>Count</th>
<th>Percent</th>
</tr>
</thead>
</table>
| Apo-Varenicline  | > 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)                  |       |       |         |
| Varenicline      | > Prevent overutilization (PT SAFETY)                                                  |       |       |         |
| Bupropion ER     | > Possible abuse or misuse by the patient (PT SAFETY)                                   |       |       |         |
| Nicotrol Oral Inhaler | > Prevent overutilization (COST-EFFECTIVENESS)                                           |       |       |         |
| Nicotrol Nasal Spray | > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) |       |       |         |
| Buprenorphine Film, SL | > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)                      |       |       |         |
| Buprenorphine/Naloxone SL | > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)                  |       |       |         |
| Zubsolv          |                                                                                       |       |       |         |
| Kloxxado nasal   |                                                                                       |       |       |         |
| Vivitrol inj     |                                                                                       |       |       |         |

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 class 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>Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</th>
<th>Promote appropriate dosing, including strength/frequency (PT SAFETY)</th>
<th>Prevent overutilization (PT SAFETY)</th>
<th>Prevent overutilization (COST-EFFECTIVENESS)</th>
<th>Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)</th>
<th>60</th>
<th>60</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>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td>60</td>
<td>60</td>
<td>100%</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>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td>14</td>
<td>14</td>
<td>100%</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>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td>55</td>
<td>55</td>
<td>100%</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>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
<td>4</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>GI Agents - PPIs</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
<td>&gt; Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)</td>
<td>11</td>
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<td>100%</td>
</tr>
<tr>
<td>Category</td>
<td>Point</td>
<td>Recommendation</td>
<td>Compliance</td>
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</tr>
<tr>
<td>EFFECTIVENESS)</td>
<td></td>
<td>&gt; Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)</td>
<td></td>
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</tr>
<tr>
<td>ANTIEMETICS - 5-HT3</td>
<td>9</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>100%</td>
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<td></td>
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<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
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<td>&gt; Prevent overutilization (PT SAFETY)</td>
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</tr>
<tr>
<td>MULTIPLE SCLEROSIS AGENTS</td>
<td>20</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>100%</td>
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<td></td>
<td></td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
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<tr>
<td></td>
<td></td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
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</tr>
<tr>
<td>ANALGESICS - OPIOID</td>
<td>65</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>92%</td>
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<td></td>
<td></td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
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<td></td>
<td></td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
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<td></td>
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<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
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<tr>
<td></td>
<td></td>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
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<tr>
<td></td>
<td></td>
<td>&gt; Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)</td>
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<tr>
<td></td>
<td></td>
<td>&gt; Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Class</td>
<td>Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>Prevent overutilization (PT SAFETY)</td>
<td>Possible abuse or misuse by the patient (PT SAFETY)</td>
<td>Prevent overutilization (COST-EFFECTIVENESS)</td>
<td>Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)</td>
<td>Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)</td>
<td>29</td>
<td>25</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------</td>
<td>--------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
<td>-----</td>
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</tr>
<tr>
<td>MIGRAINE AGENTS</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DERM - ANTIPSORIATICS</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>IMMUNOSUPPRESSANTS</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized)</td>
<td>&gt; Lack of documented efficacy at higher doses</td>
<td></td>
<td>22</td>
<td>19</td>
</tr>
</tbody>
</table>

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown
PRIOR AUTHORIZATION (PA) ANALYSIS

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical / Surgical</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical / Surgical</td>
</tr>
<tr>
<td></td>
<td>Tier 1</td>
</tr>
<tr>
<td>TOTAL Drug Count by Tier</td>
<td>1,162</td>
</tr>
<tr>
<td>PA Drug Count by Tier</td>
<td>74</td>
</tr>
<tr>
<td>% of Total PA Drugs by Tier</td>
<td>15.1%</td>
</tr>
<tr>
<td>% MED/SURG Drugs with PA</td>
<td>6.4%</td>
</tr>
<tr>
<td>Mental Health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mental Health</td>
</tr>
<tr>
<td></td>
<td>Tier 1</td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>135</td>
</tr>
<tr>
<td>Substance Use Disorder</td>
<td>Tier 1</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Use Disorder</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>PA Drug Count by Tier</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>% of Total PA Drugs by Tier</td>
<td>0.0%</td>
<td>0.0%</td>
<td>100.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>% SUD Drugs with PA</td>
<td>0.0%</td>
<td>0.0%</td>
<td>20.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>5.6%</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 pharmacy prior authorization Standard Opt-Out Formulary with ACSF - 2021**

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

- 19.9% (490 out of 2,467) of the drugs in the Medical/Surgical category
- 3.1% (6 out of 194) of the drugs in the Mental Health category
- 5.6% (1 out of 18) of the drugs in the Substance Use Disorder category

The development of pharmacy prior authorization 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 pharmacy prior authorization programs, and a client or health plan chooses which pharmacy prior authorization programs to include in the plan offering. The development of pharmacy prior authorization is based on the factors below.

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

<table>
<thead>
<tr>
<th>MH/SUD DRUG CLASSES WITH PA</th>
<th>Prior Authorization Factors</th>
<th>TOTAL Drug Count</th>
<th>Count of Drugs with PA</th>
<th>Percent of Drugs with PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIANXIETY</td>
<td></td>
<td>22</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
| ANTIDEPRESSANTS Spravato 56mg & 84mg dose | > Patient safety concerns exist/Unknown long-term safety or durability  
  > Appropriate medication uses based on national guidelines  
  > Use in appropriate patient populations                      | 55               | 2                      | 4%                       |
| ANTIPSYCHOTICS Nuplazid caps, tabs | > Appropriate medication uses based on national guidelines  
  > Limited to a specific population based on FDA-            | 65               | 2                      | 3%                       |
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Use in appropriate patient populations</th>
<th>Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</th>
<th>Potential for inappropriate, off-label use</th>
<th>Count PA</th>
<th>Count Non PA</th>
<th>Percent PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPNOTICS</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td>15</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td>Lucemyra</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>&gt; Potential for inappropriate, off-label use</td>
<td>18</td>
<td>1</td>
<td>6%</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 pharmacy 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>TOTAL Drug Count</th>
<th>Count of Drugs with PA</th>
<th>Percent of Drugs with PA</th>
</tr>
</thead>
</table>

57
<table>
<thead>
<tr>
<th>Category</th>
<th>Appropriate medication uses based on national guidelines</th>
<th>Use in appropriate patient populations</th>
<th>Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</th>
<th>14</th>
<th>11</th>
<th>79%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIVIRALS - HEPATITIS C</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>14</td>
<td>11</td>
<td>79%</td>
</tr>
<tr>
<td>ANTINEOPLASTIC &amp; ADJUNCTIVE THERAPIES</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>144</td>
<td>107</td>
</tr>
<tr>
<td>OSTEOPOROSIS AGENTS</td>
<td>&gt; Patient safety concerns exist/Unknown long-term safety or durability</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>16</td>
<td>8</td>
<td>50%</td>
</tr>
<tr>
<td>GROWTH HORMONE</td>
<td>&gt; Appropriate medication uses based on national guidelines</td>
<td>&gt; Treatment based on obtaining applicable lab values or test results</td>
<td>&gt; Use in appropriate patient populations</td>
<td>&gt; Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Category</td>
<td>Main Points</td>
<td>Risk Factor 1</td>
<td>Risk Factor 2</td>
<td>Risk Factor 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
<td>---------------</td>
<td>---------------</td>
<td>---------------</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| ANTI- NARCOLEPSY/ANTI- OBESITY/ANOREXIANTS | > Patient safety concerns exist/Unknown long-term safety or durability  
> Treatment based on obtaining applicable lab values or test results  
> Use in appropriate patient populations | 4 | 2 | 50% |
| 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 | 20 | 20 | 100% |
| ANALGESICS - OPIOID | > Use in appropriate patient populations  
> Potential for inappropriate, off-label use  
> Reduce waste, unnecessary drug use, fraud or abuse | 66 | 61 | 92% |
| 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 | 58 | 25 | 43% |
| DERM - ANTIPSORIATICS | > Patient safety concerns exist/Unknown long-term safety or durability  
> Use in appropriate patient populations | 20 | 12 | 60% |
Step Therapy (ST) for Standard Opt-Out Formulary 2021 Plan – Aetna

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical / Surgical</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>1,162</td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td>0</td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td>0.0%</td>
</tr>
<tr>
<td>% MED/SURG Drugs with ST</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown.
<table>
<thead>
<tr>
<th>Substance Use Disorder</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>Total Drug Count by Tier</td>
<td>10</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>ST Drug Count by Tier</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% of Total ST Drugs by Tier</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>% SUD Drugs with ST</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</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 step therapy Standard Opt-Out Formulary with ACSF - 2021**

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 drug category and the MED/SURG drug category, and there is no step therapy applying to any drugs in the SUD drug category. Pharmacy step therapy is applied to:
MHPAEA Summary Form

- 1.5% (36 out of 2,467) of the drugs in the Medical/Surgical category.
- 6.2% (12 out of 194) 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 UM 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 in each drug class for this plan:

<table>
<thead>
<tr>
<th>State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH/SUD DRUG CLASSES WITH ST</td>
</tr>
<tr>
<td>----------------------------</td>
</tr>
<tr>
<td>ANTIANXIETY</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
</tr>
</tbody>
</table>
MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Step Therapy Factors</th>
<th>Total Drug Count</th>
<th>Count of Drugs with ST</th>
<th>Percent of Drugs with ST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotics</td>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td>65</td>
<td>4</td>
<td>6%</td>
</tr>
<tr>
<td></td>
<td>&gt; Multiple dosage forms for the same/similar chemical entity; Availability of unique dosage forms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<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>Hypnotics</td>
<td>&gt; Promote use of most cost-effective products (generics and/or lower cost brands)</td>
<td>15</td>
<td>2</td>
<td>13%</td>
</tr>
<tr>
<td></td>
<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>ADHD</td>
<td></td>
<td>37</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>SUD</td>
<td></td>
<td>18</td>
<td>0</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 in the comparable drug classes for this plan:

<table>
<thead>
<tr>
<th>State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MED/SURG DRUG CLASSES WITH ST</strong></td>
</tr>
<tr>
<td>----------------------------------------------------------------</td>
</tr>
<tr>
<td>OSTEOPOROSIS AGENTS</td>
</tr>
<tr>
<td>Category</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
</tbody>
</table>
| Antihypertensives         | > 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 | 60    | 3     | 5%         |
| Antihyperlipidemics - Statins | > 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 | 12    | 5     | 42%        |
| Nasal agents              | > Promote use of most cost-effective products (generics and/or lower cost brands)  
                          | > Alternatives available in the drug class (including generics) used to treat the same condition | 13    | 5     | 38%        |
| Gastrointestinal agents - PPIs | > Promote use of most cost-effective products (generics and/or lower cost brands)  
                          | > Alternatives available in the drug class (including generics) used to treat the same condition | 12    | 1     | 8%         |
| Urinary antispasmodics    | > Promote use of most cost-effective products (generics and/or lower cost brands)  
                          | > Alternatives available in the drug class (including generics) used to treat the same condition | 18    | 5     | 28%        |
| GU - BPH                  | > Promote use of most cost-effective products (generics and/or lower cost brands)  
                          | > Alternatives available in the drug class (including generics) used to treat the same condition | 7     | 1     | 14%        |
**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 | 31 | 3 | 10% |

| 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 | 25 | 5 | 20% |

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

**Quantity Limits (QL) Standard Opt-Out Formulary with ACSF - 2021**

<table>
<thead>
<tr>
<th>QUANTITY LIMITS (QL) ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plan: State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical / Surgical</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Medical / Surgical Total Drug Count by Tier</td>
<td>1,162</td>
</tr>
<tr>
<td>QL Drug Count by Tier</td>
<td>223</td>
</tr>
<tr>
<td>Mental Health</td>
<td>Tier 1</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
</tr>
<tr>
<td>Total Drug Count by Tier</td>
<td>135</td>
</tr>
<tr>
<td>QL Drug Count by Tier</td>
<td>43</td>
</tr>
<tr>
<td>% of Total QL Drugs by Tier</td>
<td>66.2%</td>
</tr>
<tr>
<td>% MH Drugs with QL</td>
<td>31.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Use Disorder</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>Total Drug Count by Tier</td>
<td>10</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>QL Drug Count by Tier</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>% of Total QL Drugs by Tier</td>
<td>36.4%</td>
<td>9.1%</td>
<td>45.5%</td>
<td>0.0%</td>
<td>9.1%</td>
<td></td>
</tr>
</tbody>
</table>
### Comparative Analysis for Quantity Limits Standard Opt-Out Formulary with ACSF - 2021

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 in the MH, SUD, and MED/SURG drug categories. Quantity limits are applied to:

- 28.3% (697 out of 2,467) of the drugs in the Medical/Surgical category.
- 33.5% (65 out of 194) of the drugs in the Mental Health category.
- 61.1% (11 out of 18) 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 limits programs to include in the plan offering. The development of quantity limits is based on the factors below.

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

| State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021 |
|----------------|----------------|----------------|---------------|
| **MH/SUD DRUG CLASSES WITH QL** | **Quantity Limit Factors** | **TOTAL Drug Count** | **Count of Drugs** | **Percent of Drugs** |
| | | | | |

---

*Note: Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration*
<table>
<thead>
<tr>
<th>Prescription Category</th>
<th>Potential Issues</th>
<th>with QL</th>
<th>with QL</th>
</tr>
</thead>
</table>
| ANTIANXIETY Medications | > 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) | 22 | 17 | 77% |
| ANTIDEPRESSANTS |  | 55 | 0 | 0% |
| ANTIPSYCHOTICS | > 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) | 65 | 2 | 3% |
### MHPAEA Summary Form

#### Hypnotics

<table>
<thead>
<tr>
<th>Drug</th>
<th>Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</th>
<th>Promote appropriate dosing, including strength/frequency (PT SAFETY)</th>
<th>Prevent overutilization (PT SAFETY)</th>
<th>Possible abuse or misuse by the patient (PT SAFETY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estazolam</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Eszopiclone</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Hetlioz caps, oral susp</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Ramelteon</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Temazepam</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Triazolam</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Zaleplon</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Zolpidem tab, ER</td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
</tbody>
</table>

#### ADHD

Includes substance controlled drugs used to treat ADHD.

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

| 15 | 11 | 73% |
| 37 | 35 | 95% |
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>SUD Apo-Varenicline</th>
<th>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupropion ER</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
</tr>
<tr>
<td>Nicotrol Oral Inhaler</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
</tr>
<tr>
<td>Nicotrol Nasal Spray</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
</tr>
<tr>
<td>Buprenorphine SL, Film</td>
<td>&gt; Prevent overutilization (COST-EFFECTIVENESS)</td>
</tr>
<tr>
<td>Buprenorphine/Naloxone</td>
<td>&gt; Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized)</td>
</tr>
<tr>
<td>Zubsolv</td>
<td>&gt; Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)</td>
</tr>
<tr>
<td>Kloxxado nasal Lucemyra Vivitrol inj</td>
<td>&gt; Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)</td>
</tr>
<tr>
<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

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>
<tbody>
<tr>
<td>State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Category</th>
<th>Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</th>
<th>Promote appropriate dosing, including strength/frequency (PT SAFETY)</th>
<th>Prevent overutilization (PT SAFETY)</th>
<th>Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized)</th>
<th>Lack of documented efficacy at higher doses</th>
<th>Percent Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANTIVIRALS - HIV</strong></td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANTIVIRALS - HEPATITIS C</strong></td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES</strong></td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized)</td>
<td>&gt; Lack of documented efficacy at higher doses</td>
<td>74%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>GROWTH HORMONE</strong></td>
<td>&gt; Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)</td>
<td>&gt; Promote appropriate dosing, including strength/frequency (PT SAFETY)</td>
<td>&gt; Prevent overutilization (PT SAFETY)</td>
<td>&gt; Possible abuse or misuse by the patient (PT SAFETY)</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Class</td>
<td>Potential Concerns</td>
<td>Score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<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) | 12    |
| 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) | 9     |
| MULTIPLE SCLEROSIS AGENTS        | > Promote appropriate dosing, including strength/frequency (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY) | 20    |
## MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Category</th>
<th>Risk Indicators</th>
<th>Percentage</th>
</tr>
</thead>
</table>
| **ANALGESICS - OPIOID**       | > Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)  
> Promote appropriate dosing, including strength/frequency (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY)  
> Prevent overutilization (COST-EFFECTIVENESS)  
> Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS)  
> Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)  
> Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE) | 66 61 92% |
| **DERM - ANTIPSORIATICS**     | > Promote appropriate dosing, including strength/frequency (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY) | 20 13 65% |
| **DERM - POST-HERPETIC NEURALGIA** | > Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY)  
> Prevent overutilization (PT SAFETY)  
> Possible abuse or misuse by the patient (PT SAFETY)  
> Prevent overutilization (COST-EFFECTIVENESS) | 10 8 80% |
## MHPAEA Summary Form

<table>
<thead>
<tr>
<th>IMMUNOSUPPRESSANTS</th>
<th>&gt; Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)</th>
<th>18</th>
<th>16</th>
<th>89%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<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></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; Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; Lack of documented efficacy at higher doses</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.
MHPAEA Summary Form

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:
MHPAEA Summary Form

- Brand or generic status of the drug
- Impact of generic drugs or drugs designated to become available over-the-counter
- 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
MHPAEA Summary Form

- 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
- 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 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: Advanced Control Formulary 2021 Plan - Aetna

- Tier 1 = Preferred Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands and Generics
- Tier 4 = Preferred Specialty
- Tier 5 = Non-Preferred Specialty

<table>
<thead>
<tr>
<th>FORMULARY TIERING ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan: State of MD - AETNA - Advanced Control Formulary - 2021</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
</table>

79
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>Medical / Surgical</th>
<th>Medical / Surgical</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>
<tbody>
<tr>
<td>Drug Count by Tier</td>
<td>966</td>
<td>206</td>
<td>794</td>
<td>219</td>
<td>188</td>
<td>2,373</td>
<td></td>
<td>58.6%</td>
</tr>
<tr>
<td>% of Drug Count per Tier</td>
<td>40.7%</td>
<td>8.7%</td>
<td>33.5%</td>
<td>9.2%</td>
<td>7.9%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mental Health</th>
<th>Mental Health</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>
<tbody>
<tr>
<td>Drug Count by Tier</td>
<td>119</td>
<td>10</td>
<td>38</td>
<td>0</td>
<td>6</td>
<td>173</td>
<td></td>
<td>74.6%</td>
</tr>
<tr>
<td>% of Drug Count per Tier</td>
<td>68.8%</td>
<td>5.8%</td>
<td>22.0%</td>
<td>0.0%</td>
<td>3.5%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Use Disorder</th>
<th>Substance Use Disorder</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>
<tbody>
<tr>
<td>Drug Count by Tier</td>
<td>9</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>19</td>
<td></td>
<td>57.9%</td>
</tr>
<tr>
<td>% of Drug Count per Tier</td>
<td>47.4%</td>
<td>5.3%</td>
<td>36.8%</td>
<td>5.3%</td>
<td>5.3%</td>
<td></td>
<td></td>
<td></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

** Preferred Tier includes: Tier 1 preferred generics, Tier 2 preferred brands and Tier 4 preferred specialty

### Comparative Analysis for formulary tier designation FOR: Advanced Control Formulary 2021 Plan - Aetna

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 drug category and a comparable percentage in the SUD drug category as compared to the MED/SURG drug category.

- The Medical/Surgical category has 58.6% of the drugs at a preferred formulary tier.
- The Mental Health category has 74.6% of the drugs at a preferred formulary tier.
The Substance Use Disorder category has 57.9% of the drugs at a preferred formulary tier.

**Specialty Drug designation: Advanced Control Formulary 2021 Plan - Aetna**

<table>
<thead>
<tr>
<th>Category</th>
<th>Medical / Surgical</th>
<th>Mental Health</th>
<th>Substance Use Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Specialty Drugs per Tier</td>
<td>10.6% 5.1% 7.3% 41.8% 35.2%</td>
<td>0.0% 0.0% 0.0% 0.0% 100.0%</td>
<td>0%</td>
</tr>
<tr>
<td>Specialty Drug Count by Tier</td>
<td>54 26 37 213 179</td>
<td>0 0 0 0 6</td>
<td>0</td>
</tr>
<tr>
<td>Total Specialty Drugs</td>
<td>509</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>% Specialty</td>
<td>21.5%</td>
<td>3.5%</td>
<td>10.5%</td>
</tr>
</tbody>
</table>
Comparative Analysis for Specialty drug designation Advanced Control Formulary 2021 Plan - Aetna

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 21.5% 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 3.5% of the drugs with a Specialty drug designation.
  - The 6 drugs in the MH drug category with a Specialty drug designation include: Spravato 56mg, 84mg; Nuplazid caps/tabs; and Hetlizor caps/oral susp.
- The Substance Use Disorder category has 10.5% 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.

FORMULARY TIERING FOR: Standard Opt-Out Formulary 2021 Plan – Aetna

- Tier 1 = Preferred Generics
- Tier 2 = Preferred Brands
- Tier 3 = Non-Preferred Brands and Generics
- Tier 4 = Specialty
- Tier 5 = Non-Preferred Specialty

<table>
<thead>
<tr>
<th>Category</th>
<th>Analysis</th>
</tr>
</thead>
</table>

**FORMULARY TIERING ANALYSIS**

<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
</tr>
</tbody>
</table>
### Comparative Analysis for formulary tier designation for: Standard Opt-Out Formulary 2021 Plan – Aetna

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

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

Specialty Drug designation: Standard Opt-Out Formulary 2021 Plan – Aetna

<table>
<thead>
<tr>
<th>Category</th>
<th>Medical / Surgical</th>
<th>Mental Health</th>
<th>Substance Use Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Specialty Drug Count by Tier</td>
<td>Specialty Drug Count by Tier</td>
<td>Specialty Drug Count by Tier</td>
</tr>
<tr>
<td></td>
<td>Tier 1</td>
<td>Tier 2</td>
<td>Tier 3</td>
</tr>
<tr>
<td>Medical / Surgical</td>
<td>54</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>Mental Health</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Substance Use Disorder</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
### MHPAEA Summary Form

<table>
<thead>
<tr>
<th>% of Specialty Drugs per Tier</th>
<th>0.0%</th>
<th>0.0%</th>
<th>0.0%</th>
<th>50.0%</th>
<th>50.0%</th>
</tr>
</thead>
</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 Specialty drug designation Standard Opt-Out Formulary 2021 Plan – Aetna

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

- The Medical/Surgical category has 19.4% 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 3.1% of the drugs with a Specialty drug designation.
  - The 6 drugs in the MH drug category with a Specialty drug designation include: Spravato 56mg, 84mg; Nuplazid caps/tabs; Hetlioz caps/oral susp.
- The Substance Use Disorder category has 11.1% 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.
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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:**

**Experimental or investigational therapies**

**Covered services** include drugs, devices, treatments, or procedures from a **provider** under an “approved clinical trial” only when you have cancer or a **terminal illness**. All of the following conditions must be met:

- Standard therapies have not been effective or are not appropriate
- We determine you may benefit from the treatment

An approved clinical trial is one that meets all of these requirements:

- The Food and Drug Administration (FDA) has approved the drug, device, treatment, or procedure to be investigated or has granted it investigational new drug (IND) or group treatment IND status, when this is required
- The clinical trial has been approved by an institutional review board that will oversee it
- The clinical trial is sponsored by the National Cancer Institute (NCI) or similar federal organization and:
  - It conforms to standards of the NCI or other applicable federal organization
  - It takes place at an NCI-designated cancer center or at more than one institution
- You are treated in accordance with the procedures of that study

**Experimental or investigational**

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

**Experimental or investigational**

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

A drug, device, procedure, or treatment is **experimental or investigational** if:
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- There is not enough outcome data available from controlled clinical trials published in the peer-reviewed literature to validate its safety and effectiveness for the illness or injury involved.
- The needed approval by the FDA has not been given for marketing.
- A national medical or dental society or regulatory agency has stated in writing that it is experimental or investigational or suitable mainly for research purposes.
- It is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial. These terms have the meanings given by regulations and other official actions and publications of the FDA and Department of Health and Human Services.
- Written protocols or a written consent form used by a facility provider state that it is experimental or investigational.

### Clinical trials

<table>
<thead>
<tr>
<th>Description</th>
<th>[In-network]</th>
<th>[Out-of-network]</th>
<th>[Outside the U.S.]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental or investigational therapies</td>
<td>[Covered based on type of service and where it is received] [No charge] [after deductible, no deductible applies]</td>
<td>[Covered based on type of service and where it is received] [after deductible, no deductible applies]</td>
<td>[Covered based on type of service and where it is received] [Not covered] [after deductible, no deductible applies]</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:
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- 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:
  - 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 Polices 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
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- 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.
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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 applicable

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)
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• 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: \[
\frac{\text{[# of complaints or appeals]}}{\text{[monthly total for 12 months of membership/1000]}}
\]
- 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: \[
\frac{\text{[# of Out-of-Network requests]}}{\text{1,000 enrollees}}
\]

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
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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
14. Reimbursement for INN Providers, OON Providers, INN Facilities, OON Facilities (separately)

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 the amount a **network provider** has agreed to accept or that we have agreed to pay them or a third party vendor (including any administrative fee in the amount paid).

*[Note: Prints for PPO based and EPO based network models that have a separate cost share for non-designated network providers.]*

*Some providers are part of Aetna’s network for some Aetna plans but are not considered network providers for your plan. For those providers, the negotiated charge is the amount that provider has agreed to accept for rendering services or providing prescription drugs to members of your plan.]*

We may enter into arrangements with **network providers** or others related to:

- The coordination of care for members
- Improving clinical outcomes and efficiencies

Some of these arrangements are called:

- Value-based contracting
- Risk sharing
- Accountable care arrangements
These arrangements will not change the **negotiated charge** under this plan.

*Note: Prints for plans that include a managed prescription drug benefit.*

For **prescription** drug services:

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

**Non-Participating Provider and Facility Reimbursement**

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

**Plan language:**

**[Allowable amount]**

This is the amount of an **out-of-network provider’s** charge that is eligible for coverage. You are responsible for all charges above this amount. The **allowable amount** depends on the geographic area where you get the service or supply.

The table below shows the method for calculating the **allowable amount** for specific services or supplies:

*Note: Only one method of how allowable amount is calculated will print per service or supply. An actual percentage will replace the range when one exists. Prescription drugs and Dental expenses will print when the plan includes such benefits.*

<table>
<thead>
<tr>
<th>Service or supply:</th>
<th>Allowable amount is based on:</th>
</tr>
</thead>
</table>
| Professional services and other services or supplies not mentioned below | [Reasonable amount rate]  
[(50%-400%) of Medicare allowed rate]  
[(50%-400%) of the Aetna out-of-network rate (AONR)] |
| Services of **hospitals** and other facilities | Other than those hospital services regulated by the Health Services Cost Review Commission (HSCRC), for which the allowed amount is the rate approved by the HSCRC  
[Reasonable amount rate]  
[(50%-400%) of Medicare allowed rate] |
| **[Prescription]** drugs | [(50%-200%) of average wholesale price (AWP)] |
## Service or supply: Allowable amount is based on:

<table>
<thead>
<tr>
<th>Dental expenses</th>
<th>[50%-150%] of prevailing charge rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[50%-400%] of Aetna out-of-network rate (AONR)</td>
</tr>
<tr>
<td></td>
<td>[The reasonable amount rate]</td>
</tr>
</tbody>
</table>

### Important note:

See Special terms used, below, for a description of what the allowable amount is based on.

If the provider bills less than the amount calculated using a method above, the allowable amount is what the provider bills.

**Note:** This prints only for plans with vendor portion of National Advantage Program or the full program.

If your ID card displays the National Advantage Program (NAP) logo, your cost share may be lower when you get care from a NAP provider. These are out-of-network providers and third party vendors who have contracts with us but are not network providers. When you get care from a NAP provider, your out-of-network cost share applies.

**Note:** Only those special terms specific to allowable amount for the plan will print. For Medicare allowable rates, the standard number of days to update our system is 180.

### Special terms used:

- Aetna out-of-network rates (AONR) are our standard rates used to begin contract talks with providers in a specific geographic area. For areas where we don’t maintain AONR, we use [50%-400%] of the Medicare allowed rates.

- Average wholesale price (AWP) is the current average wholesale price of a prescription drug as listed in the Facts & Comparisons®, Medi-Span daily price updates or any other similar publication we choose to use.

- Facility charge review (FCR) rate is an amount that we determine is enough to cover the facility provider’s estimated costs for the service and leave the provider with a reasonable profit. This means for:
  - Hospitals and other facilities that report costs or cost to charge ratios to The Centers for Medicare & Medicaid Services (CMS), the FCR rate is based on what the facilities report to CMS.
Facilities that don’t report costs or cost to charge ratios to CMS, the FCR rate is based on a statewide average of these facilities.

We may adjust the formula as needed to maintain the reasonableness of the allowable amount. For example, we may make an adjustment if we determine that in a state the charges of a specific type of facility are much higher than charges of facilities that report to CMS.

- Geographic area is normally based using the first three digits of a zip code. If we believe we need more data for a particular service or supply, we may base rates on a wider geographic area such as the entire state.

- Medicare allowed rates are the rates CMS establishes for services and supplies provided to Medicare enrollees without taking into account adjustments for specific provider performance. We update our system with these when revised within [30-180] days of receiving them from CMS. If Medicare doesn’t have a rate, we use one or more of the items below to determine the rate for a service or supply:
  - The method CMS uses to set Medicare rates
  - How much other providers charge or accept as payment
  - How much work it takes to perform a service
  - Other things as needed to decide what rate is reasonable

[Note: When a plan or segment specific value isn’t available for the ranges below, the following standard value is used: 100% for anesthesia, 75% for lab, 75% for DME, 100% for meds payable under medical.]

We may make the following exceptions:

- For inpatient services, our rate may exclude amounts CMS allows for operating Indirect Medical Education (IME) and Direct Graduate Medical Education (DGME) programs
- Our rate may exclude other payments that CMS may make directly to hospitals or other providers and backdated adjustments
- For anesthesia, our rate may be at least [100%-350%] of the rate CMS establishes
- For lab, our rate may be [5%-75%] of the rate CMS establishes
For DME, our rate may be [25%-75%] of the rate CMS establishes.

For medications that are paid as a medical benefit instead of a pharmacy benefit, our rate may be [50%-100%] of the rates CMS establishes.

When the allowable amount is based on a percentage of the Medicare allowed rate, it is not affected by adjustments or incentives given to providers under Medicare programs.

[Note: When a plan or segment specific value isn't available for the ranges below, the following standard is used: remove ‘[50th-95th]’ and change ‘[30-180 days]’ to 180 days.]

- [Prevailing charge rate is the [50th-95th] percentile value reported in a database prepared by FAIR Health®, a non-profit company. FAIR Health may change these periodically. We update our systems within [30-180] days of receiving them from FAIR Health. If the database becomes unavailable, we may substitute a different, comparable database. If the alternate data source doesn’t contain a value for a service or supply, we will base the allowable amount on the Medicare allowed rate.]

[Note: Only one method of how reasonable amount rate is calculated will print per service or supply. An actual percentage will replace the range when one exists. A service or supply will print when included in the plan. The current standard for each service or supply is: replace ‘[50th-95th]’ with “The” for professional services, use 100% for inpatient and outpatient hospital charges, use 100% for inpatient and outpatient charges that aren’t from a hospital.]

- [Reasonable amount rate means your plan has established a rate amount as follows:

<table>
<thead>
<tr>
<th>Service or supply:</th>
<th>Reasonable amount rate is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional services</td>
<td>[50th-95th] percentile value reported in a database prepared by FAIR Health</td>
</tr>
<tr>
<td>Inpatient and outpatient hospital charges</td>
<td>Other than those hospital services regulated by the Health Services Cost Review Commission (HSCRC), for which the allowable amount is the rate approved by the HSCRC</td>
</tr>
<tr>
<td></td>
<td>[50%-500%] of Medicare allowed rate</td>
</tr>
<tr>
<td></td>
<td>[The FCR rate]</td>
</tr>
<tr>
<td></td>
<td>[Note: Prints when the plan requests it.]</td>
</tr>
<tr>
<td></td>
<td>[What the provider bills]</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Service or supply:</th>
<th>Reasonable amount rate is:</th>
</tr>
</thead>
</table>
| Inpatient and outpatient charges that are not from a hospital | [[50%-500%] of Medicare allowed rate]  
[The FCR rate]  
[Note: Prints when the plan requests it.]  
[What the provider bills]| |

**Our reimbursement policies**

We have the right to apply our reimbursement policies to all out-of-network services. This may affect the **allowable amount**. When we do this, we consider:

- The length and difficulty of a service
- Whether additional expenses are needed, when multiple procedures are billed at the same time
- Whether an assistant surgeon is needed
- If follow up care is included
- Whether other conditions change or make a service unique
- Whether any of the services described by a claim line are part of or related to the primary service provided, when a charge includes more than one claim line
- The educational level, licensure or length of training of the **provider**

We base our reimbursement policies on our review of:

- CMS National Correct Coding Initiative (NCCI) and other external materials that say what billing and coding practices are and aren’t appropriate
- Generally accepted standards of medical and dental practice
- The views of **physicians** and dentists practicing in relevant clinical areas

We use commercial software to administer some of these policies. Policies may differ for professional services and facility services.
Get the most from 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’ tool or ‘Payment Estimator’ tool on the Aetna website. The website may contain additional information that can help you determine the cost of a service or supply. [End section note]

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
- 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)

**Non-Participating Facility 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)

**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.

**Participating Facility Reimbursement**
Aetna monitors the application of this NQTL through:
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- 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.

Non-Participating Provider Reimbursement
Aetna monitors the application of this NQTL through:
- 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.

Non-Participating Facility 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