MHPAEA Summary Form

Under a federal law called the Mental Health Parity and Addiction Equity Act (MHPAEA), Aetna Health 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 Health 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 NQTLs are and how the health plans achieve parity are discussed below.

1. **Definition of Medical Necessity**

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

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

If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. The Claims Administrator reserves the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be within the Claims Administrator's sole discretion. The Claims Administrator develops and maintains clinical policies that describe the Generally Accepted Standards of Medical Practice scientific evidence, prevailing medical standards and clinical guidelines supporting its determinations regarding specific services. These clinical policies as developed by the Claims Administrator are revised from time to time. Aetna publishes information concerning utilization review and our medical necessity criteria here: https://www.aetna.com/health-care-professionals/utilization-management.html Within that site, there is a section dedicated specially to the criteria used for behavioral health conditions, which can be found here: https://www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html We also publish clinical policy bulletins concerning services we may or may not cover, including behavioral health services that may be excluded on grounds that they are experimental and investigational, which detail the evidentiary bases for our coverage or exclusion determinations: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html **Covered services:** All inpatient, outpatient and emergency care services **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 4	If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. The Claims Administrator reserves the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be within the Claims Administrator's sole discretion. The Claims Administrator develops and maintains clinical policies that describe the Generally Accepted Standards of Medical Practice scientific evidence, prevailing medical standards and clinical guidelines supporting its determinations regarding specific services. These clinical policies as developed by the Claims Administrator are revised from time to time. Aetna publishes information concerning utilization review and our medical necessity criteria here: https://www.aetna.com/health-care-professionals/utilization-management.html Within that site, there is a section dedicated specially to the criteria used for behavioral health conditions, which can be found here: https://www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html We also publish clinical policy bulletins concerning services we may or may not cover, including behavioral health services that may be excluded on grounds that they are experimental and investigational, which detail the evidentiary bases for our coverage or exclusion determinations: https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html **Covered services:** All inpatient, outpatient and emergency care services **Plan language:**

Medical necessity[, referral] and precertification requirements

[Note: The second bullet will print when the contract holder's plan doesn't require referrals. The third bullet will print when the contract holder'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**
- [You get the service from a **network provider**]
- [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

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.

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**

➢ Section # 170 / Form # HI COC00170 05/ Page # 3

➢ Section # 110 / Form # HI COC00110 05 / Page # 4

Medical necessity[, referral] and precertification requirements

[Note: The second bullet will print when the contract holder's plan doesn't require referrals. The third bullet will print when the contract holder'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**
- [You get the service from a **network provider**]
- [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**.]
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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.

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

Medically necessary, medical necessity Health care services that we determine a **provider**, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that we determine are: • In accordance with generally accepted standards of medical practice • Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease • Not primarily for the convenience of the patient, **physician**, or other health care **provider** • Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease Generally accepted standards of medical practice means: • Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community • Following the standards set forth in our clinical policies and applying clinical judgment	bulletins and other information at **https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html** ➢ Section # 170 / Form # HI COC00170 05/ Page # 3 **Medically necessary, medical necessity** Health care services that we determine a **provider**, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that we determine are: • In accordance with generally accepted standards of medical practice • Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease • Not primarily for the convenience of the patient, **physician**, or other health care **provider** • Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease Generally accepted standards of medical practice means: • Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community • Following the standards set forth in our clinical policies and applying clinical judgment

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

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

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

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

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

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

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

All other factors share these sources:

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

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

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

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

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

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

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

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

- Emergency:
  - M/S: CPBs
  - MH/SUD: CPBs

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

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

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

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

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

Clinical Policy Bulletins are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other relevant new information warrants more frequent review. The CPB development process includes annual assessment of new and emerging evidence-based

information, including clinical information related to health equity, such as that related to race, ethnicity, gender, and underserved populations. Each time a CPB is updated, a comprehensive search of the peer-reviewed, published medical literature is performed to determine if there is a change in the experimental and investigational status or medical necessity of the medical technologies addressed. If the Clinical Policy Research and Development Team determines that new evidence or other information has emerged to warrant a change in Aetna's clinical policy, a revised CPB draft is prepared. If no new evidence has emerged that would warrant a change in Aetna's position, the CPB may be updated with additional supporting background information and references. Each revised CPB is submitted to Aetna's Clinical Policy Council for review and approval. Additional changes to the revised or updated draft CPB may be made upon the recommendations of the Clinical Policy Council.

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

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

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

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

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

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

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

2. **Prior Authorization Review Process**

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

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

Proton beam Radiotherapy, and Electric or Motorized Wheelchairs and Scooters). Please refer to most up-to date Participating Provider Precertification List for Medical/Surgical services and the Behavioral Health Precertification List for MH/SUD services, which is subject to change from time to time. See https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants.. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For Medical/Surgical: All outpatient all other non-palliative procedures, services, devices, and therapies on the National Precertification List (NPL) https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 4-7	Proton beam Radiotherapy, and Electric or Motorized Wheelchairs and Scooters). Please refer to most up-to date Participating Provider Precertification List for Medical/Surgical services and the Behavioral Health Precertification List for MH/SUD services, which is subject to change from time to time. See https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For Medical/Surgical: All outpatient all other non-palliative procedures, services, devices, and therapies on the National Precertification List (NPL) https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 4-7

Medical necessity[, referral] and precertification requirements ***[Note: The second bullet will print when the contract holder's plan doesn't require referrals. The third bullet will print when the contract holder'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** • [You get the service from a **network provider**] • [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**. We will accept a **precertification** from a prior carrier for **covered services** under this plan that require **precertification**. Contact us for further details. Your network **physician** or **PCP** is responsible for obtaining any necessary **precertification** before you get the care. **Network providers** cannot bill you if they fail to ask us for **precertification**. But if your **physician** or **PCP** requests **precertification** and we deny it, and you still choose to get the care, you will have to pay for it yourself. Timeframes for **precertification** are listed below. For **emergency services**, **precertification** is not required, but you should notify us as shown.	**Medical necessity[, referral] and precertification requirements** ***[Note: The second bullet will print when the contract holder's plan doesn't require referrals. The third bullet will print when the contract holder'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** • [You get the service from a **network provider**] • [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**. We will accept a **precertification** from a prior carrier for **covered services** under this plan that require **precertification**. Contact us for further details. Your network **physician** or **PCP** is responsible for obtaining any necessary **precertification** before you get the care. **Network providers** cannot bill you if they fail to ask us for **precertification**. But if your **physician** or **PCP** requests **precertification** and we deny it, and you still choose to get the care, you will have to pay for it yourself. Timeframes for **precertification** are listed below. For **emergency services**, **precertification** is not required, but you should notify us as shown.

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

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

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

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

For an inpatient **stay** in a facility, we will tell you, your **physician** and the facility about your **precertified** length of **stay**. If your **physician** recommends that you stay longer, the extra days will need to be **precertified**. You, your **physician**, or the facility will need to call us as soon as reasonably possible, but no later than the final authorized day. We will tell you and your **physician** in writing of an approval or denial of the extra days.
If you or your **provider** request **precertification** and we don't approve coverage, we will tell you why and explain how you or your **provider**

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

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

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

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

For an inpatient **stay** in a facility, we will tell you, your **physician** and the facility about your **precertified** length of **stay**. If your **physician** recommends that you stay longer, the extra days will need to be **precertified**. You, your **physician**, or the facility will need to call us as soon as reasonably possible, but no later than the final authorized day. We will tell you and your **physician** in writing of an approval or denial of the extra days.
If you or your **provider** request **precertification** and we don't approve coverage, we will tell you why and explain how you or your **provider**

may request review of our decision. See the *Complaints, claim decisions and appeal procedures* section. *Types of services that require precertification* **Precertification** is required for inpatient **stays** and certain outpatient services and supplies. Contact us to get a list of the services that require **precertification**. The list may change from time to time. Sometimes you or your **provider** may want us to review a service that doesn't require **precertification** before you get care. This is called a predetermination, and it is different from **precertification**. Predetermination means that you or your **provider** requests the pre-service clinical review of a service that does not require **precertification**. ➢ Section # 170 / Form # HI COC00170 05 / Page # 4, 7 ***[Note: References to precertification or precertified may be changed to pre-authorization or pre-authorized or pre-approval or pre-approved]*** **[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.] ***[Note: Prints if included in the policyholder's plan design.]***	may request review of our decision. See the *Complaints, claim decisions and appeal procedures* section. *Types of services that require precertification* **Precertification** is required for inpatient **stays** and certain outpatient services and supplies. Contact us to get a list of the services that require **precertification**. The list may change from time to time. Sometimes you or your **provider** may want us to review a service that doesn't require **precertification** before you get care. This is called a predetermination, and it is different from **precertification**. Predetermination means that you or your **provider** requests the pre-service clinical review of a service that does not require **precertification**. ➢ Section # 170 / Form # HI COC00170 05 / Page # 4, 7 ***[Note: References to precertification or precertified may be changed to pre-authorization or pre-authorized or pre-approval or pre-approved]*** **[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.] ***[Note: Prints if included in the policyholder's plan design.]***

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

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

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

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

- Patient safety: Considers whether precertification can minimize potential harm to a member, particularly for life changing procedures that are irreversible post-surgery.
- Clinical quality control: Refers to ensuring a provider and proposed treatment are qualified and appropriate so that the possibility of adverse outcomes is reduced.
- Marked variation in provider utilization patterns: Refers to there being a significant range providers' utilization of the service, drug or device, suggesting that some of the utilization may be unnecessary.
- Incorrect utilization: Refers to the potential that a given service, drug or device is not appropriate for the member's condition.
- Application of Clinical Policy Bulletin (CPB) requirements: Refers to the opportunity to make determinations required under Aetna's CPBs and other clinical policies pertaining to the experimental/investigational nature of a service, appropriate use of new/changing technology, step therapy, or site of service.
- Standards of industry practice: Refers to what other health insurers and administrators have decided to be appropriate in terms of precertification.

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

Factors for retaining a Service to the NPL:

- ROI 3:1 or greater - retain
- ROI 2 to 2.9:1

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

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

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

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

Sources:

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

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

Evidentiary Standards:

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

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

Process for Developing the National Precertification List (NPL):

The NPL is used by participating providers to identify which MH/SUD and M/S services require precertification for INN coverage. The NPL Committee is responsible for determining which services to add, retain or remove from the NPL. It comprises clinicians and other subject matter experts representing both MH/SUD and M/S expertise. Proposed additions or changes to the NPL are submitted to the NPL Committee. The Committee considers the factors listed above and decides whether to add or remove the service. Also, the Committee annually reviews services on the NPL to decide whether to retain or remove them. Any factors and Extenuating Factors relied upon in making the decision must be documented; this allows for validation that they are being applied comparably, and not more stringently, to MH/SUD services.

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

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

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

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

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

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

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

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

Evaluation of determinations adding to or removing MH/SUD and M/S services from the NPL: Precertification is required for all inpatient admissions for both MH/SUD and M/S services. (The exceptions for hospice and short maternity/newborn stays are not significant enough to suggest a parity concern.) Precertification is not required for any MH/SUD or M/S Outpatient-Office Visits. As for Outpatient-All Other benefits, there are only 5 MH/SUD services in that classification subject to precertification compared to approximately 34 categories of M/S services, and no new MH/SUD services have been added to the NPL in the past 5 years (since the framework for inclusion on the NPL was formalized). In the NPL Committee's 2021 annual retention review, no MH/SUD or M/S services that met the ROI were removed from the NPL. All MH/SUD services met the ROI and were retained on the NPL. From this information it is clear that the factors and sources used to add to, retain or remove a service from the NPL are comparable, and not more stringent, for MH/SUD services.

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

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

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

services, which is subject to change from time to time. See https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/2023_Precert_List.pdf All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For Medical/Surgical: All outpatient all other non-palliative procedures, services, devices, and therapies on the National Precertification List (NPL) https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/2023_Precert_List.pdf **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 12 **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	https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf All UM factors, processes, strategies, and evidentiary standards, both MH/SUD and medical/surgical, are singularly developed in unison through the coordination efforts of the Parity Taskforce who leverages both MH/SUD and medical/surgical subject matter experts in factor development and ongoing review, and the National Precertification List (NPL) Committee—a group of clinicians and other subject matter experts representing both MH/SUD and medical/surgical expertise then applies these determinants. **Covered services:** A detailed analytical framework is not provided for Inpatient because this NQTL applies to all non-palliative procedures, services, devices, and therapies for both medical/surgical and MH/SUD; as such administration of this NQTL is identical. For MH/SUD: All outpatient all other non-palliative procedures, services, devices, and therapies on the Behavioral Health Precertification List (MH/SUDPL) https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 12 **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. You will receive a decision as soon as possible but no later than 1 working day after

working day before the original approval ends. You will receive a decision as soon as possible but no later than 1 working day after receipt of the information necessary to make the determination. **Concurrent care claim reduction or termination** A concurrent care claim reduction or termination occur when we decide to reduce or stop payment for an already approved course of treatment. We will notify you of such a determination. You will have enough time to file an appeal. Your coverage for the service or supply will continue until you receive a final appeal decision from us or an external review organization if the situation is eligible for external review.	receipt of the information necessary to make the determination. **Concurrent care claim reduction or termination** A concurrent care claim reduction or termination occur when we decide to reduce or stop payment for an already approved course of treatment. We will notify you of such a determination. You will have enough time to file an appeal. Your coverage for the service or supply will continue until you receive a final appeal decision from us or an external review organization if the situation is eligible for external review.

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

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

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

Factors used in determining how concurrent review is performed:

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

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

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

Sources:

The processes and evidentiary standards used in determining what services are subject to precertification and, therefore, to concurrent review, are described in Aetna's Prior Authorization NQTL Comparative Analysis.

Evidentiary Standards for Performing Concurrent Review:
Aetna's concurrent review processes are designed in accordance with National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, and applicable state and federal law.

Strategy for Performing Concurrent Review:
For both MH/SUD and M/S services, the guiding strategy behind concurrent review relies upon the clinical reviewers' exercise of their clinical judgment, guided by clinical criteria, to determine whether to authorize coverage for additional units of care. They rely upon their training and experience, informed by the member's medical history, clinician progress notes and discharge plans, to assess "severity" and "complexity" (as those terms are used within Aetna's National Clinical Services policies and procedures and clinical guidelines).

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

The processes and evidentiary standards used in determining what services are subject to precertification and, therefore, to concurrent review, are described in Aetna's Prior Authorization NQTL Comparative Analysis.

Process for Developing the National Precertification List (NPL):
The NPL is used by participating providers to identify which MH/SUD and M/S services require precertification for INN coverage. The NPL Committee is responsible for determining which services to add, retain or remove from the NPL. It comprises clinicians and other subject matter experts representing both MH/SUD and M/S expertise. Proposed additions or changes to the NPL are submitted to the NPL Committee. The Committee considers the factors listed above and decides whether to add or remove the service. Also, the Committee annually reviews services on the NPL to decide whether to retain or remove them. Any factors and Extenuating Factors relied upon in making the decision must be documented; this allows for validation that they are being applied comparably, and not more stringently, to MH/SUD services.

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

Process for Performing Concurrent Review:
Concurrent review is initiated before the authorized coverage period under the initial precertification or previous concurrent review expires. Updated information about the patient's condition, progress and treatment/discharge plan is obtained from the provider. Concurrent reviews are performed by licensed clinicians who are RNs, licensed clinical social workers or physicians. The licensed clinician may approve coverage for

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

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

The same factors and sources apply to MH/SUD and M/S benefits in deciding which services are subject to precertification and, by extension, to concurrent review. The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling concurrent review requests for MH/SUD and M/S benefits. Thus, as written this NQTL is applied comparably, and not more stringently, to MH/SUD benefits.

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

Aetna's Inter-Rater Reliability and Internal Quality Review processes provide a way to evaluate whether precertification and concurrent review of MH/SUD and M/S services is performed comparably, and not more stringently for MH/SUD, in operation. In that process, Medical Directors and Utilization Management Clinicians are audited for accuracy and consistency in their application of utilization management criteria. These reports show that both Medical and Behavioral Health Medical Directors and clinicians are performing precertification and concurrent review accurately and consistently.

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

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

4. **Retrospective Review Process**

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

Med/Surg Benefits	MH/SUD Benefits
Retrospective review is a utilization review service performed by licensed healthcare professionals to determine coverage after treatment has been given. The intent is to determine medical necessity, appropriateness of treatment, and determine benefits and eligibility. For OON services, Aetna performs retrospective review on OON Inpatient services that were not pre-certified and OON Outpatient All-Other services that are on the member precertification list and were not precertified. For INN services, Aetna performs retrospective review in the following limited circumstances: when an INN psychiatric hospital or other MH/SUD or M/S facility that is not a Hospital or Children's Hospital failed to precertify or give timely notice of inpatient admission; when required by state law or Aetna's contract with a facility; when provider precertification requirements are waived due to a state or federal disaster declaration; or when there is a valid reason for failure to precertify or give timely notice (e.g., member was unable to provide insurance information at the time). For Emergency services, Aetna performs retrospective review on "emergency" M/S and MH/SUD services where the diagnosis code signifies a non-emergent condition. **M/S services NQTL applies to:** All OON M/S inpatient services, and all outpatient-all other services on the Member Precertification List, that were not precertified. INN inpatient services when provided by a facility (other than a hospital or children's hospital) that failed to precertify or give timely notice of admission	Retrospective review is a utilization review service performed by licensed healthcare professionals to determine coverage after treatment has been given. The intent is to determine medical necessity, appropriateness of treatment, and determine benefits and eligibility. For OON services, Aetna performs retrospective review on OON Inpatient services that were not pre-certified and OON Outpatient All-Other services that are on the member precertification list and were not precertified. For INN services, Aetna performs retrospective review in the following limited circumstances: when an INN psychiatric hospital or other MH/SUD or M/S facility that is not a Hospital or Children's Hospital failed to precertify or give timely notice of inpatient admission; when required by state law or Aetna's contract with a facility; when provider precertification requirements are waived due to a state or federal disaster declaration; or when there is a valid reason for failure to precertify or give timely notice (e.g., member was unable to provide insurance information at the time). For Emergency services, Aetna performs retrospective review on "emergency" M/S and MH/SUD services where the diagnosis code signifies a non-emergent condition. **MH/SUD services NQTL applies to:** All OON MH/SUD inpatient services, and outpatient-all other services on the Member Precertification List, that were not precertified. INN inpatient services when provided by a psychiatric hospital or facility (other than a hospital or children's hospital) that failed to precertify or give timely notice of admission

"Emergency" M/S services on the NonEmergent ER Diagnosis List **Plan language:** Refer to the plan language for precertification. https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/2023_Precert_List.pdf **Plan language: Section # 40 / Form # HI COC00040 05 / Page # 5** **Emergency services** When you experience an **emergency medical condition**, you should go to the nearest emergency room. You can also dial 911 or your local emergency response service for medical and ambulance help. **Covered services** include only outpatient services to evaluate and stabilize an **emergency medical condition** in a **hospital** emergency room. You can get **emergency services** from **network providers** or **out-of-network providers**. If your **physician** decides you need to stay in the **hospital** (emergency admission) or receive follow-up care, these are not **emergency services**. Different benefits and requirements apply. You are covered for follow-up care only when your **physician** or **primary care physician (PCP)** provides or coordinates it. If your **emergency medical condition** includes surgery, we will cover follow-up care with the surgeon at network cost sharing if: • It's related to the condition for which the surgery was done • It is consulted with your **physician** or **primary care physician (PCP)** Please refer to the *How your plan works – Medical necessity[, referral] and precertification requirements* section and the *Coverage*	"Emergency" M/S services on the NonEmergent ER Diagnosis List **Plan Language:** Refer to the plan language for precertification. https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/bh_precert_list.pdf **Plan language: Section # 40 / Form # HI COC00040 05 / Page # 5** **Emergency services** When you experience an **emergency medical condition**, you should go to the nearest emergency room. You can also dial 911 or your local emergency response service for medical and ambulance help. **Covered services** include only outpatient services to evaluate and stabilize an **emergency medical condition** in a **hospital** emergency room. You can get **emergency services** from **network providers** or **out-of-network providers**. If your **physician** decides you need to stay in the **hospital** (emergency admission) or receive follow-up care, these are not **emergency services**. Different benefits and requirements apply. You are covered for follow-up care only when your **physician** or **primary care physician (PCP)** provides or coordinates it. If your **emergency medical condition** includes surgery, we will cover follow-up care with the surgeon at network cost sharing if: • It's related to the condition for which the surgery was done • It is consulted with your **physician** or **primary care physician (PCP)** Please refer to the *How your plan works – Medical necessity[, referral] and precertification requirements* section and the *Coverage*

and exclusions section that fits your situation (for example, *Hospital care* or *Physician services*). You can also contact us or your network **physician** or **primary care physician** (**PCP**). **Non-emergency services** If you go to an emergency room for what is not an **emergency medical condition**, the plan may not cover your expenses. See the schedule of benefits for this information.	*and exclusions* section that fits your situation (for example, *Hospital care* or *Physician services*). You can also contact us or your network **physician** or **primary care physician** (**PCP**). **Non-emergency services** If you go to an emergency room for what is not an **emergency medical condition**, the plan may not cover your expenses. See the schedule of benefits for this information.

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

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

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

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

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

The factors used in determining how retrospective review is performed are:

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

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

Sources:
Some of the processes and evidentiary standards used in determining what services are subject to retrospective review are described in Aetna's Prior Authorization NQTL Comparative Analysis. Additionally, Aetna reviews its contracts with participating facility providers and monitors state

and federal laws and disaster declarations to determine when the standard obligation for the provider to give timely notice of an admission must be waived; when the obligation to give timely notice of an admission is waived, then Aetna will perform retrospective review instead of imposing a payment penalty on the participating provider. Regarding the list of non-emergent diagnosis codes that trigger a retrospective review of "emergency" services, that list is maintained by Aetna's Payment Policy and Coding Committee. The Medical Directors on the PPDC reviewICD10 and DSM-V coding descriptions and apply their clinical training, experience and judgment to assess whether the symptoms would typically cause a "prudent layperson" (as that term is defined in federal law) to believe emergency care was needed.

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

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

Evidentiary Standards for Performing Retrospective Review:
The evidentiary standards/sources for Aetna's retrospective review processes are National Committee for Quality Assurance (NCQA) utilization management standards for Health Plan Accreditation and Managed Behavioral Health Organization accreditation, applicable state and federal law.

Strategy for Performing Retrospective Review:
For both MH/SUD and M/S services, the guiding strategy behind retrospective review relies upon the clinical reviewers' exercise of their clinical judgment based on their training and experience, guided by clinical criteria and informed by the member's medical history, to determine whether to approve coverage for care already provided.

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

Process for Developing the National Precertification List (NPL):
The NPL is used by participating providers to identify which MH/SUD and M/S services require precertification for INN coverage. The NPL Committee is responsible for determining which services to add, retain or remove from the NPL. It comprises clinicians and other subject matter experts representing both MH/SUD and M/S expertise. Proposed additions or changes to the NPL are submitted to the NPL Committee. The Committee considers the factors listed above and decides whether to add or remove the service. Also, the Committee annually reviews services on the NPL to decide whether to retain or remove them. Any factors and Extenuating Factors relied upon in making the decision must be documented; this allows for validation that they are being applied comparably, and not more stringently, to MH/SUD services.

The same factors and sources, and the same National Clinical Services Policies and Procedures, apply to handling retrospective review requests for MH/SUD and M/S benefits. Regarding "emergency" services that are subject to retrospective review, of the 1495 diagnosis codes that trigger retrospective review, only 80 (5%) are for MH/SUD conditions. Thus, as written this NQTL is applied comparably, and not more stringently, to MH/SUD benefits.

Process for Performing Retrospective Review:
Retrospective review is performed after services have already been provided. It is done by licensed clinicians who are RNs, licensed clinical social workers or physicians. The licensed clinician may approve coverage or, if unable to approve coverage, will refer the case to a Medical Director who is a physician or to a consultant psychiatrist/ psychologist/ board certified behavior analyst-doctoral (BCBA-D) for further review and action. Consultant psychiatrists/ psychologists/ BCBA-Ds use the available clinical information to approve a coverage request or, when unable to approve, make a level of care or service recommendation and forward the recommendation to the Medical Director or the designated psychologist/BCBA-D for issuance of the coverage determination. The licensed clinician or Medical Director draws upon his or her training and expertise in applying the applicable clinical review criteria to the request. (See Aetna's Medical Necessity NQTL Comparative Analysis for more information about clinical review criteria.) The retrospective review determination is made and communicated to the provider/member according to the established timeframes. In some circumstances the treating provider may have a peer-to-peer consultation with a physician.

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

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

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

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

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

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

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

5. Emergency Services

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

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

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

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

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

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

6. **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;

NQTL's Applicable to Med/Surg Benefits in Prescription Classification	NQTL's Applicable to MH/SUD Benefits in Prescription Classification
Pharmacy Prior Authorization: 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. **Plan Language:** 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: This will print when the contract holder'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**.] 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.	**Pharmacy Prior Authorization:** Pharmacy prior authorization is utilized in drug classes where the potential for use for unapproved indications exists, the potential for inappropriate over- or under-utilization exists, or when safety concerns exist with a drug or drug class. Cost may also be a consideration in determining if prior authorization is appropriate. In effect since 1/1/2020 Aetna added coverage state specific benefit code to bypass formulary exclusions, bypass Prior Authorization on the "Medication Assisted Therapy" list to meet the ASAM criteria. **Plan Language:** 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: This will print when the contract holder'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**.]

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. MED/SURG drugs with Prior Auth: (Below are examples of MED/SURG drugs with Prior Auth) ADVANCED CONTROL FORMULARY Sovaldi	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.

Harvoni Lenvima Xtandi Sprycel Forteo Prolia Sunosi Aubagio Gilenya Xtampza ER Nucynta Enbrel Humira Taltz Skyrizi Targretin Tacrolimus STANDARD OPT-OUT FORMULARY Sovaldi Harvoni Lenvima Xtandi Sprycel Forteo Prolia Armodafinil Aubagio Gilenya Xtampza ER Nucynta Enbrel Humira Taltz Skyrizi	MH/SUD drugs with Prior Auth: ADVANCED CONTROL FORMULARY Loreev XR Sertraline caps Spravato 56mg & 84mg dose Abilify Mycite tabs Chlorpromazine Invega Hafyera Lybalvi Nuplazid caps, tabs Rexulti Versacloz Vraylar cap/Pack Hetlioz caps, oral susp Azstarys STANDARD OPT-OUT FORMULARY Spravato 56mg & 84mg dose Nuplazid caps, tabs Hetlioz caps, oral susp Lucemyra **Pharmacy Step Therapy (ST):** Step therapy is a pharmacy UM strategy typically employed in therapeutic classes with broad generic availability. Step Therapy is generally used to promote the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent, with the potential for reduced cost from greater utilization of generics and/or lower cost brands. **Plan Language:** **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.

Targretin Tacrolimus **Pharmacy Step Therapy (ST):** Step therapy is a pharmacy UM strategy typically employed in therapeutic classes with broad generic availability. Step Therapy is generally used to promote the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent, with the potential for reduced cost from greater utilization of generics and/or lower cost brands. **Plan Language:** **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 **provider** 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	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 **provider** 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: This will print when the contract holder's plan requires drug precertification, step therapy, or both. Appropriate bracketed terms will print based on the contract holder's plan.]*** [Contact us or go online to get the most up-to-date [**precertification** requirements] [and] [list of **step therapy** drugs].] ***[Note: "or may seek to continue the same cost share. . ." and "If we remove a drug from the drug guide. . ." will print for plans that include a managed prescription drug benefit.]*** Sometimes your prescriber or your pharmacist may ask for a medical exception for drugs that are not covered or for which coverage was denied[, or may seek to continue the same cost share when a **prescription** drug or device is moved to a higher cost share tier]. [If we remove a drug from the **drug guide** or move a drug or device to a higher cost share tier, we will give you and your prescriber 30 days

[Note: This will print when the contract holder's plan requires drug precertification, step therapy, or both. Appropriate bracketed terms will print based on the contract holder's plan.] [Contact us or go online to get the most up-to-date [**precertification** requirements] [and] [list of **step therapy** drugs].] ***[Note: "or may seek to continue the same cost share. . ." and "If we remove a drug from the drug guide. . ." will print for plans that include a managed prescription drug benefit.]*** Sometimes your prescriber or your pharmacist may ask for a medical exception for drugs that are not covered or for which coverage was denied[, or may seek to continue the same cost share when a **prescription** drug or device is moved to a higher cost share tier]. [If we remove a drug from the **drug guide** or move a drug or device to a higher cost share tier, we will give you and your prescriber 30 days advance notice with the information on how to request a medical exception.]. You, someone who represents you or your prescriber can contact us. You will need to provide us with clinical documentation. Any exception granted is based upon an individual and is a case-by-case decision that will not apply to other members. ***[Note: The text regarding tiers will print for plans that include a managed prescription drug benefit.]*** We will cover a **prescription** drug or device not listed in the **drug guide**[, or cover it at the same cost share when it is moved to a higher tier] if any of the following conditions is met: • There is no equivalent **prescription** drug or device in the **drug guide** [in a lower tier]; • An equivalent prescription drug or device in the **drug guide** [in a lower tier]: • Has been ineffective in treating your disease or condition; or	advance notice with the information on how to request a medical exception.]. You, someone who represents you or your prescriber can contact us. You will need to provide us with clinical documentation. Any exception granted is based upon an individual and is a case-by-case decision that will not apply to other members. ***[Note: The text regarding tiers will print for plans that include a managed prescription drug benefit.]*** We will cover a **prescription** drug or device not listed in the **drug guide**[, or cover it at the same cost share when it is moved to a higher tier] if any of the following conditions is met: • There is no equivalent **prescription** drug or device in the **drug guide** [in a lower tier]; • An equivalent prescription drug or device in the **drug guide** [in a lower tier]: • Has been ineffective in treating your disease or condition; or • Has caused or is likely to cause an adverse reaction or other harm to you ***[Note: The contraceptive drug bullet will only be removed for religious exemption plans.]*** • [A contraceptive **prescription** drug or device not in the **drug guide** is **medically necessary** for you to adhere to the appropriate use of the **prescription** drug or device.] • Section # 170 / Form # HI COC00170 05 / Page # 4, 7 ***[Note: References to precertification or precertified may be changed to pre-authorization or pre-authorized or pre-approval or pre-approved]***

• Has caused or is likely to cause an adverse reaction or other harm to you ***[Note: The contraceptive drug bullet will only be removed for religious exemption plans.]*** • [A contraceptive **prescription** drug or device not in the **drug guide** is **medically necessary** for you to adhere to the appropriate use of the **prescription** drug or device.] • Section # 170 / Form # HI COC00170 05 / Page # 4, 7 ***[Note: References to precertification or precertified may be changed to pre-authorization or pre-authorized or pre-approval or pre-approved]*** 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	In effect since 1/1/2020 Aetna added coverage state specific benefit code to bypass Step Therapy drugs on the "Medication Assisted Therapy" list to meet the ASAM criteria. Step therapy is a pharmacy UM strategy employed in therapeutic classes with broad generic availability. Step Therapy is used to promote the use of the most cost-effective products in the therapeutic class, provided efficacy and safety are equivalent, with the potential for reduced cost from greater utilization of generics and/or lower cost brands. 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

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. **MED/SURG drugs with Step Therapy:** (Below are examples of MED/SURG drugs with ST) ADVANCED CONTROL FORMULARY Januvia SymlinPen Fosamax Plus D Tekturna HCT Myrbetriq Cardura XL Savella Aimovig Emgality Calcipotriene	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. MH/SUD drugs with Step Therapy: ADVANCED CONTROL FORMULARY Desvenlafaxine ER Trintellix Zolpidem ER Dyanavel XR Quillichew ER Quillivant XR STANDARD OPT-OUT FORMULARY Fetzima cap/Pack Pexeva Trintellix Viibryd tab/Pack

STANDARD OPT-OUT FORMULARY Fosamax Plus D Tekturna HCT Altoprev Beconase AQ Rabeprazole sprinkle caps Myrbetriq Cardura XL Zembrace Lumigan Zioptan **Pharmacy Quantity Limits (QL):** Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered for the drug, or the number of prescription claims for the drug over a period of 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. **Plan Language:** **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. The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the	Latuda Rexulti Vraylar cap/Pack Belsomra Edluar] **Pharmacy Quantity Limits (QL):** Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered for the drug, or the number of prescription claims for the drug over a period of 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. **Plan Language:** **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. Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered for the drug, or the number of prescription claims for the drug over a period of time. Pharmacy QLs are applied to each drug class regardless of whether the intended use is for a MH/SUD condition or a MED/SURG condition. Pharmacy QLs apply to both generic and brand drugs.

same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions. Quantity Limits establish a maximum quantity of certain medications that will be covered by the client's plan over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered by the client for the dug, or the number of prescription claims for the drug over a period of time. When a member's claim exceeds the established limit for the drug, the claim will be rejected by the CVS Caremark processing system. Messaging is provided to the dispensing pharmacy advising that the plan's drug limitation has been exceeded or that a prior authorization is required for coverage of an additional quantity. The decision to implement quantity limit is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the quantity or duration of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions. Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are written to effectively manage	The processes and strategies used in the development of CVS Caremark standard Utilization Management (UM) programs are the same for drugs used in MH/SUD conditions as for drugs used in MED/SURG conditions. Quantity Limits establish a maximum quantity of certain medications that will be covered by the client's plan over a specified time period. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount covered by the client for the dug, or the number of prescription claims for the drug over a period of time. When a member's claim exceeds the established limit for the drug, the claim will be rejected by the CVS Caremark processing system. Messaging is provided to the dispensing pharmacy advising that the plan's drug limitation has been exceeded or that a prior authorization is required for coverage of an additional quantity. The decision to implement quantity limit is based on principles that consider the place in therapy for the drug, how the drug might be used in clinical practice, and the quantity or duration of therapy needed by most patients. UM Criteria are developed based upon published clinical evidence supporting the different uses of a drug and coverage conditions are not affected or altered by the medication's intended area of utilization. For example, UM criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions. Development of UM Criteria includes a coverage summary and algorithm of questions that when completed, renders a coverage decision. Criteria include coverage for uses supported by evidence-based medicine and Standard of Care sources. Coverage conditions are based on safety considerations in black box warnings and/or contraindications in the product labeling if these situations can be

utilization and minimize cost associated with uses that are outside the scope of the plan's pharmacy benefit. MED/SURG drugs with Quantity Limits: (Below are examples of MED/SURG drugs with QL) ADVANCED CONTROL FORMULARY Descovy Lamivudine Viread Harvoni Sovaldi Junel Mirena Norditropin Omeprazole Lansoprazole Ondansetron Granisetron Aubagio Gilenya Lortab Tramadol Aimovig Emgality Taltz Skyrizi Cyclosporine Sirolimus STANDARD OPT-OUT FORMULARY Descovy Lamivudine Viread Harvoni	effectively managed through a PA process. Additional safety-related concerns may be added at the recommendation of the External Clinical Expert(s). Standard UM Criteria are written to effectively manage utilization and minimize cost associated with uses that are outside the scope of the plan's pharmacy benefit. MH/SUD drugs with Quantity Limits: (Below are examples of MED/SURG drugs with QL) ADVANCED CONTROL FORMULARY Alprazolam tabs, ER tab, ODT Chlordiazepoxide Clonazepam tab, ODT Diazepam oral conc, oral soln, tabs Lorazepam oral conc, tabs Desvenlafaxine ER Nuplazid caps, tabs Flurazepam Hetlioz caps, oral susp Ramelteon Temazepam Amphetamine Dextroamphetamine Vyvanse Methylphenidate Buprenorphine/naloxone SL tab, film Bupropion ER Nicotrol oral inhaler, nasal spray Kloxxado nasal spray Vivitrol injection STANDARD OPT-OUT FORMULARY Alprazolam tabs, ER tab, ODT Chlordiazepoxide Clonazepam tab, ODT

Sovaldi Lenvima Xtandi Sprycel Norditropin Omeprazole Lansoprazole Ondansetron Granisetron Aubagio Gilenya Lortab Tramadol Taltz Skyrizi Lidocaine patch Cyclosporine Sirolimus	Diazepam oral conc, oral soln, tabs Lorazepam oral conc, tabs Nuplazid caps, tabs Flurazepam Hetlioz caps, oral susp Ramelteon Temazepam Amphetamine Dextroamphetamine Vyvanse Methylphenidate Buprenorphine/naloxone SL tab, film Bupropion ER Nicotrol oral inhaler, nasal spray Kloxxado nasal spray Vivitrol injection

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

Factors: Prior Authorization:

Pharmacy Prior Authorization (PA)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Factors	• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability • Applicable lab values or other test results required for appropriate treatment • Appropriate medication uses for indications or conditions based on national guidelines • Use in appropriate patient populations	• 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

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

Pharmacy Prior Authorization (PA)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
	therapy, second line therapy, or concurrent therapy. First line therapy refers to the initial recommended treatment for a disease or illness. o **Evidentiary Standard**: FDA-approved indications; recommended off-label uses o **Sources**: published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Potential for inappropriate or off-label use –** National treatment guidelines and the Food and Drug Administration's evaluation of these drugs determine their safety and efficacy for a particular disease or illness and define recommended duration of therapy o **Evidentiary Standard**: controlled substance status; reports of off label use o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Opportunity for optimizing patient outcomes and to ensure treatment goals of the drug are being met** – Confirm patient is responding to therapy, e.g., A1C or cholesterol targets are being met. o **Evidentiary Standard**: improvement of symptoms from baseline; reduction of elevated blood levels (e.g., cholesterol) o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Requirement for additional treatment supportive therapies -** Additional supportive therapies, in addition to medications, may be recommended in the guidelines as the most effective treatment approach for a given condition. These therapies include but are not limited to behavioral counseling, diet therapy, case management, and other standard non-drug supportive therapies. o **Evidentiary Standard**: behavioral counseling, diet therapy o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug	

Pharmacy Prior Authorization (PA)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
	information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Reduce waste, unnecessary drug use, fraud, or abuse**: practices that, directly or indirectly, result in unnecessary costs, overusing services. o **Evidentiary Standard**: complex treatment regimens requiring dose titration o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria	

Factors: Step Therapy:

Pharmacy Step Therapy (ST)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Factors	• Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands • Clinical safety and adverse events based on FDA approved labeling, national clinical guideline recommendations, and other evidentiary standards • Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards • Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms • Availability of therapeutic alternatives, including generics, used to treat the same condition	• Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands • Clinical safety and adverse events based on FDA approved labeling, national clinical guideline recommendations, and other evidentiary standards • Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards • Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms • Availability of therapeutic alternatives, including generics, used to treat the same condition

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

Factors: Pharmacy Quantity Limits:

Pharmacy Quantity Limits (QL)		
	Medical/Surgical	**Mental Health / Substance Use Disorder**
Factors	• Enhance patient safety o Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA o To promote appropriate drug dosing, including strength and frequency o To prevent overutilization o When abuse or misuse by the patient is possible o 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 o Prevention of overutilization o Discouragement of misuse and waste through dose efficiency QLs, which ensure that the appropriate tablet strength is utilized o Lack of documented efficacy/unknown efficacy at higher doses • Discourage misuse, waste, and abuse o Maximum daily dosing or maximum duration of use limits	• Enhance patient safety o Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA o To promote appropriate drug dosing, including strength and frequency o To prevent overutilization o When abuse or misuse by the patient is possible o 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 o Prevention of overutilization o Discouragement of misuse and waste through dose efficiency QLs, which ensure that the appropriate tablet strength is utilized o Lack of documented efficacy/unknown efficacy at higher doses • Discourage misuse, waste, and abuse o Maximum daily dosing or maximum duration of use limits
Definitions of Factors	• **Enhance patient safety:** Applying quantity limits based on this factor affords an opportunity to ensure that safety and treatment goals of the drug are being met: National treatment guidelines and the Food and Drug Administration's evaluation of these drugs determine their safety and efficacy for a particular disease or illness and define recommended duration of therapy o **Evidentiary Standard**: Safety concerns noted by the manufacturer in clinical trials or in post-marketing reports o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of	

Pharmacy Quantity Limits (QL)	
	UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Cost and cost effectiveness:** Excessive quantity is defined as a quantity that exceeds the recommended dosing regimen or the recommended duration of therapy. Quantity limits are based on FDA-approved indications, standard clinical practice, and guidelines: Dosing recommended treatment for a disease or illness. National treatment guidelines and the FDA's evaluation of these drugs determine the appropriate dosing based on safety and efficacy for a particular disease or illness. o **Evidentiary Standard**: lower-cost, safe and effective drugs available to treat a condition o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, comparison of similar drugs in terms of safety and efficacy, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria • **Discourage misuse, waste, and** abuse: practices that, directly or indirectly, result in unnecessary costs, overusing services. o **Evidentiary Standard**: many strengths available for a drug that requires individualized dosing o **Sources**: FDA product labeling, published peer-reviewed clinical literature, approved drug compendia, accepted clinical practice guidelines, standards of care noted in clinical literature, appropriate clinical drug information from other sources, annual review of UM criteria, review of any new criteria, updates and annual review of UM criteria, review and approval of prior authorization coverage criteria

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

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

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

MED/SURG SOURCES
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
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J. Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

2. Appropriate medication uses for indications or conditions based on national guidelines

MED/SURG SOURCES
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology

C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
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3. Use in appropriate patient populations

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

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

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

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

D. Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care, American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Management of Heart Failure
E. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references
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C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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5. Potential for inappropriate or off-label use

MED/SURG SOURCES
A. US Food and Drug Administration (FDA) product labeling

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

J. Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

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

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

G. Comparison of similar drugs in terms of safety and efficacy
H. Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department
I. Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area
J. Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

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

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

C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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8. Reduce waste, unnecessary drug use, fraud, or abuse

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

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

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

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A. US Food and Drug Administration (FDA) product labeling
B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex
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3. Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards

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A. US Food and Drug Administration (FDA) product labeling

B. Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of the American College of Cardiology
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4. Multiple dosage forms available for the same or similar chemical entities, or availability of unique dosage forms

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

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Pharmacy Quantity Limits:

1. Enhance patient safety

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2. Cost and cost effectiveness

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C. Approved drug compendia, including American Hospital Formulary Service Drug Information (AHFS-DI), Lexicomp, Clinical Pharmacology, Micromedex

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3. Discourage misuse, waste, and abuse

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

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

In the minutes dated 10/27/2021 a decision was made to add the M/S drug Avonex to the ACF and SOO formularies with PA. The approved criteria included the following requirements: diagnosis; prescriber restrictions; concomitant therapy restrictions. In this case, the criteria reflect the application of the following factors: appropriate medication uses for indications or conditions based on national guidelines, use in appropriate patient populations, and use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines. Factors and sources used were not explicit in the minutes, however clinical drug information reviewed by PBM clinicians showed Avonex is approved to treat a certain population of patients diagnosed with multiple sclerosis and has the potential for serious side effects.

During the period of 2021 to 2022, there were no MH/SUD drugs proposed for the addition of prior authorization criteria.

PA Factor	**Sources for Avonex – M/S**
Appropriate medication uses for indications or conditions based on national guidelines	Practice Guideline Recommendations: Disease-modifying Therapies for Adults with Multiple Sclerosis (aan.com) https://www.aan.com/Guidelines/home/GuidelineDetail/898
Use in appropriate patient populations	DailyMed - AVONEX- interferon beta-1a kit AVONEX PEN- interferon beta-1a injection, solution AVONEX- interferon beta-1a injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d70a39cc-de15-4c12-a1ec-8063b69ea0e1
Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples: Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 6, 2023. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/

	US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/

In the minutes dated 6/1/2022, a decision was made to add the M/S drug Qulipta to the ACF formulary with ST. The approved criteria included requirements for a two-month trial of one generic therapeutic alternative from any of four different drug classes. In this case, the criteria reflect the application of the following factors: promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands and clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards. Factors and sources used were not explicit in the minutes, however clinical drug information reviewed by PBM clinicians showed there are other therapeutic classes of medications with efficacy in migraine prevention that are considered first-line and have generics available.

Similarly, in the minutes dated 2/24/2021, a decision was made to add ST to the MH drug Ambien on the ACF formulary. The approved criteria included requirements for a one-month trial of the generic for Ambien or one other generic alternative. In this case, the criteria reflect the application of the following factors: promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands and availability of therapeutic alternatives, including generics, used to treat the same condition. Factors and sources used were not explicit in the minutes, however clinical drug information reviewed by PBM clinicians showed there are generics available for Ambien and other hypnotics in the same therapeutic class.

ST Factor	**Sources for Qulipta – M/S**	**Sources for Ambien – MH**
Promote the use of the most cost-effective products in the therapeutic class; promote generics and/or lower cost brands	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login

	Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples: Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 25, 2023. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/	Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com Published peer-reviewed clinical literature, accepted clinical practice guidelines, standards of care, and government health agencies. Examples: Peer-Reviewed literature and standards of care are accessible via academic databases that enable users to execute searches across multiple journals. National Library of Medicine. Health Data Sources. https://www.nlm.nih.gov/oet/ed/stats/03-700.html Accessed October 25, 2023. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ US Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org Centers for Disease Control and Prevention. https://www.cdc.gov/index.htm US Food and Drug Administration. https://www.fda.gov/
Clinical efficacy, based on FDA approved labeling, national clinical guideline recommendations and other evidentiary standards	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm

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

Pharmacy Quantity Limits:

In the minutes dated 6/2/2021 a decision was made to add the M/S drug Gralise to the ACF and SOO formularies with QL. The approved criteria indicated a quantity that aligns with the recommended daily dose and is specific to each available strength. In this case, applying a quantity limit reflects the application of the following factors: enhance patient safety, discourage misuse, waste and abuse, and cost-effectiveness. Factors and sources used were not explicit in the minutes, however clinical drug information reviewed by PBM clinicians showed the need to titrate the dose of Gralise to the effective level and that the dose should be adjusted in certain patients with comorbid conditions.

Similarly, in the minutes dated 10/27/2021 a decision was made to add the MH drug Qelbree to the ACF formulary with QL. The approved criteria indicated a quantity that is limited to 90 capsules for a one-month supply. In this case, applying a quantity limit reflects the application of the following factors: enhance patient safety, discourage misuse, waste and abuse, and cost-effectiveness. Factors and sources used were not explicit in the minutes, however clinical drug information reviewed by PBM clinicians showed Qelbree is available in multiple strengths, the dose needs to be titrated and it has potential to increase suicidal thoughts and behavior.

QL Factor	**Sources for Gralise – M/S**	**Sources for Qelbree – MH**
enhance patient safety	DailyMed - GRALISE- gabapentin tablet, film coated GRALISE- gabapentin kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=466273b1-c9fc-3930-c94b-aa11394d5140	DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a
discourage misuse, waste and abuse	DailyMed - GRALISE- gabapentin tablet, film coated GRALISE- gabapentin kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=466273b1-c9fc-3930-c94b-aa11394d5140	DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a
cost-effectiveness	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia

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

Advanced Control Formulary 2021 - Aetna

Pharmacy Prior Authorization (PA): Advanced Control Formulary 2021

PRIOR AUTHORIZATION (PA) ANALYSIS							
Plan: State of MD - AETNA - Advanced Control Formulary - 2021							
Category		Analysis					
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	TOTAL Drug Count by Tier	966	206	794	219	188	2,373
	PA Drug Count by Tier	75	25	350	216	174	840
	% of Total PA Drugs by Tier	8.9%	3.0%	41.7%	25.7%	20.7%	
	% MED/SURG Drugs with PA	7.8%	12.1%	44.1%	98.6%	92.6%	**35.4%**
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	119	10	38	0	6	173
	PA Drug Count by Tier	0	2	9	0	6	17
	% of Total PA Drugs by Tier	0.0%	11.8%	52.9%	0.0%	35.3%	
	% MH Drugs with PA	0.0%	20.0%	23.7%	0.0%	100.0%	**9.8%**
Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	9	1	7	1	1	19
	PA Drug Count by Tier	0	0	0	0	0	0
	% of Total PA Drugs by Tier	0.0%	0.0%	0.0%	0.0%	0.0%	
	% SUD Drugs with PA	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**

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

Comparative Analysis for 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:

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTIANXIETY Loreev XR	> Use in appropriate patient populations > Potential for inappropriate, off-label use	22	1	5%
ANTIDEPRESSANTS Sertraline caps 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	47	3	6%
ANTIPSYCHOTICS Abilify Mycite tabs Chlorpromazine Invega Hafyera Lybalvi Nuplazid caps, tabs Rexulti	> Appropriate medication uses based on national guidelines > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	63	10	16%

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
Versacloz Vraylar cap/Pack				
HYPNOTICS Hetlioz caps, oral susp	> Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use	12	2	17%
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:

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTIVIRALS - HEPATITIS C	> Appropriate medication uses based on national guidelines > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	14	11	79%
ANTINEOPLASTIC & ADJUNCTIVE THERAPIES	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	153	116	76%
OSTEOPOROSIS AGENTS	> Patient safety concerns exist/Unknown long-term safety or durability > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	16	8	50%
GROWTH HORMONE	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use	4	4	100%
ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	> Patient safety concerns exist/Unknown long-term safety or durability > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations	5	4	80%
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%

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANALGESICS - OPIOID	> Use in appropriate patient populations > Potential for inappropriate, off-label use > Reduce waste, unnecessary drug use, fraud or abuse	65	60	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	56	28	50%
DERM - ANTIPSORIATICS	> Patient safety concerns exist/Unknown long-term safety or durability > Use in appropriate patient populations	16	13	81%
DERM - ANTINEOPLASTICS	> Patient safety concerns exist/Unknown long-term safety or durability > Appropriate medication uses based on national guidelines > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	8	4	50%
DERM - IMMUNOSUPPRESSANTS	> Appropriate medication uses based on national guidelines > Use in appropriate patient populations	2	2	100%

Note: Drug classes are defined by Generic Product Indicator codes associated with noted classes and drug products shown
The MIA Instructions for Step 5 do not describe an exact required methodology that needs to be used for counting drugs with UM in a formulary analysis, and there is no requirement to analyze PA data with respect to tier placement. The processes for developing and applying prior authorization to drugs used to treat MH, SUD or MED/SURG conditions is done without regard to a drug's formulary tier placement. The processes of tier placement and UM development are done independently and one does not rely on or relate to the other. Prior authorization is applied to a drug when it is determined to be appropriate based on the attributes of the drug or the condition being treated (as described in Step 1). It is not applied with the goal of staying above or below a threshold within a given tier, that is determined by a comparison of two disparate groups. Please see explanations below.

PRIOR AUTHORIZATION Advanced Control Formulary – 2021	**MIA analysis of data not discussed/explained by Aetna where the data appear to indicate that more stringency in application of PAs to MH/SUD medications**

• 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	Of all medications with PA, there is a greater proportion of MH medications with PA in Tiers 2, 3 and 5 compared to M/S medications with PA. Specifically: 1. Tier 2: 11.8% of all MH medications with PA versus 3% of all M/S medications with PA appears to suggest that fewer preferred branded MH medications are accessible without PA 2. Tier 3: 52.9% of all MH medications with PA versus 41.7% of all M/S medications with PA 3. Tier 5: 35.3% of all MH medications with PA versus 20.7% of all M/S medications with PA The total number of M/S medications on the formulary is 14 times higher than the total number of MH medications, therefore a comparison of their percentages alone does not illustrate the complete picture. **1. Tier 2:** There are 10 MH drugs on Tier 2 and 8 of them are available without PA. The 2 drugs with PA are actually 2 dosage forms of the same drug Vraylar (capsule and titration pack)[1]. There is a therapeutic alternative for Vraylar available on Tier 1 without PA. The factors that apply to Vraylar are Appropriate medication uses based on national guidelines, and Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents. **2. Tier 3:** There are 38 MH drugs on Tier 3 and 29 of them are available without PA. Of the 9 that require PA, 5 of them have an alternative of the same drug (either in the same or an alternative dosage form) available without PA on Tier 1 (Loreev XR[2], Sertraline caps[3], Versacloz[4], Chlorpromazine oral conc[5], Ability Mycite[6]) and one has an alternative available without PA on Tier 3 (Invega Hafyera[7]). The remaining 3 drugs (Azstarys[8], Lybalvi[9], Rexulti[10]) have therapeutic alternatives available without PA, and have the same factors applying as Vraylar: Appropriate medication uses based on national guidelines, and Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents. 3. **Tier 5:** There are actually 3 different MH drugs (Spravato[11], Nuplazid[12], Hetlioz[13]) that make up the 6 items that require PA on Tier 5, since they are available in different strengths/dosage forms (Spravato 56mg and 84mg, Nuplazid tabs and caps, Hetlioz caps and oral susp).

	There are only 17 MH drugs that require PA (less than 10% of all MH drugs on the formulary). These drugs on Tier 5 are specialty drugs that are indicated for use in limited, specific populations, require a screening tool or test results for appropriate diagnosis, require close monitoring to ensure safe use, and Nuplazid and Spravato have black box warnings. These factors make it appropriate for these drugs to require prior authorization. [1]DailyMed - VRAYLAR- cariprazine capsule, gelatin coated VRAYLAR- cariprazine kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b5f7c65-aa2d-452a-b3db-bc85c06ff12f [2]DailyMed - LOREEV XR- lorazepam capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=227734c1-bf01-9607-73ea-5a1f38a89bd9 [3]DailyMed - SERTRALINE HCL- sertraline hydrochloride capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8c8bcba9-eaeb-aa44-f9ea-b580de55a439 [4]DailyMed - VERSACLOZ- clozapine suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2592c9a8-fd74-4e0d-a895-b07b014cf355 [5]DailyMed - CHLORPROMAZINE HYDROCHLORIDE concentrate (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9398a0b4-e08b-4eb7-9f31-97d4f384427a [6]DailyMed - ABILIFY MYCITE- aripiprazole tablet with sensor (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e8787c3f-5e41-42d1-8091-44b56346620f [7]DailyMed-INVEGAHAFYERA-paliperidonepalmitateinjection, suspension, extended release (nih.gov)

	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6cd61892-d2cb-434d-83ed-5c1b2c4e7a0b [8]DailyMed-AZSTARYS-serdexmethylphenidateanddexmethylphenidate capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=00b5e716-5564-4bbd-acaf-df2bc45a5663 [9] DailyMed - LYBALVI- olanzapine and samidorphan l-malate tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=32ffddd1-4e2b-45d9-9b36-bb730167ec80 [10]DailyMed - REXULTI- brexpiprazole tablet REXULTI- brexpiprazole kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2d301358-6291-4ec1-bd87-37b4ad9bd850 [11]DailyMed - SPRAVATO- esketamine hydrochloride solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d81a6a79-a74a-44b7-822c-0dfa3036eaed [12]DailyMed - NUPLAZID- pimavanserin tartrate capsule NUPLAZID- pimavanserin tartrate tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e6bea44-57d6-4bac-9328-46e1ee59f83b [13]DailyMed - HETLIOZ- tasimelteon capsule HETLIOZ LQ- tasimelteon suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90
Standard Opt-Out Formulary – 2021	**MIA Analysis**

• 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	4. Tier 5: 100% of all MH medications with PA versus 35.1% of all M/S medications with PA where NONE of the non-preferred specialty MH medications are available without PA where nearly two-thirds of non-preferred MS medications are available without PA As above in the ACF formulary, the 6 items on Tier 5 are the same specialty drugs that are indicated for use in limited, specific populations, require a screening tool or test results for appropriate diagnosis, require close monitoring to ensure safe use, and Spravato and Nuplazid have black box warnings. These factors make it appropriate for these drugs to require prior authorization.

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

STEP THERAPY ANALYSIS							
Plan: State of MD - AETNA - Advanced Control Formulary - 2021							
Category		Analysis					
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	966	206	794	219	188	2,373
	ST Drug Count by Tier	1	27	15	0	0	43
	% of Total ST Drugs by Tier	2.3%	62.8%	34.9%	0.0%	0.0%	
	% MED/SURG Drugs with ST	0.1%	13.1%	1.9%	0.0%	0.0%	**1.8%**
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	119	10	38	0	6	173
	ST Drug Count by Tier	0	1	5	0	0	6
	% of Total ST Drugs by Tier	0.0%	16.7%	83.3%	0.0%	0.0%	
	% MH Drugs with ST	0.0%	10.0%	13.2%	0.0%	0.0%	**3.5%**

	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
Substance Use Disorder	Total Drug Count by Tier	9	1	7	1	1	19
	ST Drug Count by Tier	0	0	0	0	0	0
	% of Total ST Drugs by Tier	0.0%	0.0%	0.0%	0.0%	0.0%	
	% SUD Drugs with ST	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**

* 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:

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIANXIETY		22	0	0%

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIDEPRESSANTS Desvenlafaxine ER Trintellix	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	47	2	4%
ANTIPSYCHOTICS		63	0	0%
HYPNOTICS Zolpidem ER	> 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%
ADHD Dyanavel XR Quillichew ER Quillivant XR	> 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	29	3	10%
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 step therapy in the comparable drug classes for this plan:

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIDIABETICS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	70	14	20%

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

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

The MIA Instructions for Step 5 do not describe an exact required methodology that needs to be used for counting drugs with UM in a formulary analysis, and there is no requirement to analyze ST data with respect to tier placement. The processes for developing and applying step therapy to drugs used to treat MH, SUD or MED/SURG conditions is done without regard to a drug's formulary tier placement. The processes of tier placement and UM development are done independently and one does not rely on or relate to the other. Step therapy is applied to a drug when it is determined to be appropriate based on the attributes of the drug or the condition being treated (as described in Step 1). It is not applied with the goal of staying above or below a threshold within a given tier, that is determined by a comparison of two disparate groups. Two results that are both less than 4% or 7%, respectively, are considered comparable when other NQTL totals are much higher. Also, 3.5% represents only 6 MH drugs in the ACF formulary, and 6.2% represents 12 MH drugs in the SOO formulary, compared to 43 and 36 drugs, respectively, for M/S. Please see explanations below.

STEP THERAPY **Advanced Control Formulary – 2021**	**MIA analysis of data not discussed/explained by Aetna where the data appear to indicate that more stringency in application of ST to MH/SUD medications**
• 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.	1. Tier 3: 83.3% of all MH medications with ST versus 34.9% of all M/S medications with step therapy appears to suggest that fewer non-preferred branded MH medications are available without ST There are 38 MH drugs on Tier 3 and 33 of them are available without ST. The 5 drugs with ST on Tier 3 (Desvenlafaxine ER[1], Zolpidem ER[2], Dyanavel XR[3], Quillivant XR[4] and Quillichew ER[5]) are different dosage forms or therapeutic alternatives of generic drugs that are available on Tier 1 without ST. These 5 drugs display the factors of: 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; and Alternatives available in the drug class (including generics) used to treat the same condition, which indicates that it is appropriate to apply ST. [1]DailyMed - DESVENLAFAXINE ER tablet, film coated, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8a834c66-846e-38a8-e053-2a95a90a4035 [2]DailyMed - ZOLPIDEM TARTRATE EXTENDED-RELEASE- zolpidem tartrate tablet, film coated, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2977f646-8a5a-4e7b-94e1-0b0c0c5478ba

	[3]DailyMed - DYANAVEL XR- amphetamine suspension, extended release DYANAVEL XR- amphetamine tablet, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ae304b29-0b40-40ec-ad0d-76b742d4a9b9 [4]DailyMed-QUILLIVANTXR-methylphenidatehydrochloride suspension, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c2dc2109-44a6-4797-b04e-18761dd9d45a [5]DailyMed - QUILLICHEW ER- methylphenidate hydrochloride tablet, chewable, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=defc1205-8e90-4b1e-b862-05e4c35c7364
Standard Opt-Out Formulary – 2021	**MIA Analysis**
• 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.	1. Tier 2: 75% of all MH medications with ST versus 25% of all M/S medications with ST appears to suggest that fewer preferred branded MH medications are accessible without ST The 9 drugs with ST on Tier 2 (Viibryd tabs and starter pack[6], Trintellix[7], Fetzima caps and titration pack[8], Vraylar caps and pack[9], Latuda[10] and Belsomra[11]) are therapeutic alternatives of generic drugs that are available on Tier 1 without ST. These 9 drugs display the factors of: 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; and Alternatives available in the drug class (including generics) used to treat the same condition, which indicates that it is appropriate to apply ST. [6]DailyMed - VIIBRYD- vilazodone hydrochloride tablet VIIBRYD- vilazodone hydrochloride kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4c55ccfb-c4cf-11df-851a-0800200c9a66 [7]DailyMed - TRINTELLIX- vortioxetine tablet, film coated (nih.gov)

	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1a5b68e2-14d0-419d-9ec6-1ca97145e838 [8]DailyMed - FETZIMA- levomilnacipran hydrochloride capsule, extended release FETZIMA- levomilnacipran hydrochloride kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f371258d-91b3-4b6a-ac99-434a1964c3af [9]DailyMed - VRAYLAR- cariprazine capsule, gelatin coated VRAYLAR- cariprazine kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b5f7c65-aa2d-452a-b3db-bc85c06ff12f [10]DailyMed - LATUDA- lurasidone hydrochloride tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=afad3051-9df2-4c54-9684-e8262a133af8 [11]DailyMed - BELSOMRA- suvorexant tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e5b72731-1acb-45b7-9c13-290ad12d3951

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

QUANTITY LIMITS (QL) ANALYSIS							
Plan: State of MD - AETNA - Advanced Control Formulary - 2021							
Category		Analysis					
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	966	206	794	219	188	2,373
	QL Drug Count by Tier	219	62	121	209	172	783
	% of Total QL Drugs by Tier	28.0%	7.9%	15.5%	26.7%	22.0%	

	% MED/SURG Drugs with QL	22.7%	30.1%	15.2%	95.4%	91.5%	**33.0%**
Mental Health	**Mental Health**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	119	10	38	0	6	173
	QL Drug Count by Tier	38	3	12	0	4	57
	% of Total QL Drugs by Tier	66.7%	5.3%	21.1%	0.0%	7.0%	
	% MH Drugs with QL	31.9%	30.0%	31.6%	0.0%	66.7%	**32.9%**
Substance Use Disorder	**Substance Use Disorder**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	9	1	7	1	1	19
	QL Drug Count by Tier	4	1	5	0	1	11
	% of Total QL Drugs by Tier	36.4%	9.1%	45.5%	0.0%	9.1%	
	% SUD Drugs with QL	44.4%	100.0%	71.4%	0.0%	100.0%	**57.9%**

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

Comparative Analysis for Quantity Limits 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:

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
ANTIANXIETY Alprazolam tabs, 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%

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
HYPNOTICS Estazolam Eszopiclone Flurazepam Hetlioz caps, oral susp Ramelteon Temazepam Triazolam Zaleplon Zolpidem tab, ER tab	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	12	11	92%
ADHD Includes the controlled substance drugs used to treat ADHD.	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	29	27	93%

State of MD-AETNA Advanced Control Formulary				
MH/SUD DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
SUD Apo-Varenicline Varenicline Bupropion ER Nicotrol Oral Inhaler Nicotrol Nasal Spray Buprenorphine Film, SL Buprenorphine/Naloxone SL Zubsolv Kloxxado nasal Vivitrol inj	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	19	11	58%

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:

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
ANTIVIRALS - HIV	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	60	60	100%
ANTIVIRALS - HEPATITIS C	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	14	14	100%

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
CONTRACEPTIVES	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	55	55	100%
GROWTH HORMONE	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS)	4	4	100%
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)	11	11	100%
ANTIEMETICS - 5-HT3	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	9	9	100%
MULTIPLE SCLEROSIS AGENTS	> Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	20	20	100%

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
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)	65	60	92%
MIGRAINE AGENTS	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS)	29	25	86%
DERM - ANTIPSORIATICS	> Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	16	13	81%

State of MD-AETNA Advanced Control Formulary				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
IMMUNOSUPPRESSANTS	> 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) > Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized) > Lack of documented efficacy at higher doses	22	19	86%

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

The MIA Instructions for Step 5 do not describe an exact required methodology that needs to be used for counting drugs with UM in a formulary analysis, and there is no requirement to analyze QL data with respect to tier placement. The processes for developing and applying quantity limits to drugs used to treat MH, SUD or MED/SURG conditions is done without regard to a drug's formulary tier placement. The processes of tier placement and UM development are done independently, and one does not rely on or relate to the other. Quantity limits are applied to a drug when it is determined to be appropriate based on the attributes of the drug or the condition being treated (as described in Step 1). It is not applied with the goal of staying above or below a threshold within a given tier, that is determined by a comparison of two disparate groups. Please see explanations below.

QUANTITY LIMITS Advanced Control Formulary – 2021	**MIA analysis of data not discussed/explained by Aetna where the data appear to indicate that more stringency in application of QLs to MH/SUD medications**
• 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.	1. **Tier 1**: 66.7% of all MH medications and 36.4% of all SUD medications with QL versus 28% of all M/S medications with QL 2. **Tier 3**: 21.1% of all MH medications and 45.5% of all SUD medications with QLs versus 15.5% of all M/S medication with QL The SUD category represents a very small number of drugs, most of which are used to treat tobacco use and opioid use disorders. Three of the 4 SUD drugs with QL on Tier 1 (buprenorphine sl tab[1], buprenorphine/naloxone sl tab and film[2]) are also opioids themselves, and have a significant potential for abuse or misuse, indicating the need for close monitoring. Four of the 5 SUD drugs with QL on Tier 3

	(Nicotrol nasal spray[3], Nicotrol inhaler[4], Apo-varenicline[5] and Varenicline[6]) are used to treat tobacco use disorder, and one is used in the treatment of opioid use disorder. Quantity limits have been placed on these drugs to align with treatment guidelines, as well as FDA dosing recommendations. These limits reflect the factors of enhance patient safety, discourage misuse, waste and abuse, and cost-effectiveness, making it appropriate to apply QL. In the MH category, the antianxiety class also contains controlled substances with potential for misuse and abuse (**Antianxiety agents with QL on Tier 1**: alprazolam (3 dosage forms)[7], chlordiazepoxide[8], clonazepam tabs and ODT[9], clorazepate[10], diazepam (3 dosage forms)[11], lorazepam tabs and oral concentrate[12], oxazepam[13]. **Antianxiety agents with QL on Tier 1**: alprazolam (2 dosage forms)[7] Hypnotics is another class that contains controlled substances and chronic use of these agents for sleep disorders may actually be a sign of underlying physical or psychiatric disorders, it is important to monitor their use in order to assess the need for further evaluation of the condition. **Hypnotics with QL on Tier 1**: estazolam[14], eszopiclone[15], flurazepam[16], ramelteon[18], temazepam[19], triazolam[20], zaleplon[21], zolpidem tabs[22]. **Hypnotics with QL on Tier 3**: zolpidem ER tabs[22]). Most of the drugs used to treat ADHD are schedule II controlled substances, which have the highest potential for abuse among FDA approved prescription drugs. (**ADHD agents with QL on Tier 1**: dextroamphetamine (3 dosage forms)[23], Zenzedi[24], methamphetamine[26], amphetamine/dextroamphetamine[27], atomoxetine[29], dexmethylphenidate (4 dosage forms)[30], methylphenidate (5 dosage forms)[31], (**ADHD agents with QL on Tier 3:** amphetamine[32], Dyanavel XR[33], Qelbree[34], methylphenidate CR tabs, chew tabs[35], Quillivant XR[36], Quillichew ER[37], Azstarys[38]). Quantity limits have been placed on these drugs to align with treatment guidelines, as well as FDA dosing recommendations. These limits also reflect the factors of enhance patient safety, discourage misuse, waste and abuse, and cost-effectiveness, making it appropriate to apply QL. [1]DailyMed - BUPRENORPHINE HCL SL- buprenorphine hcl tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=77d3c308-58b8-2ab0-e053-2991aa0a4918 [2]DailyMed - BUPRENORPHINE AND NALOXONE SUBLINGUAL FILM- buprenorphine and naloxone film (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4210afeb-474c-d842-d68e-af7e0021851a [3]DailyMed - NICOTROL- nicotine spray, metered (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=acb7d02d-249b-4645-ac1b-8ff9a56dd244

	[4]DailyMed - NICOTROL- nicotine inhalant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f32f9c92-cbb4-483b-9e70-0b6e4567824f [5]DailyMed - APO-VARENICLINE- varenicline kit APO-VARENICLINE- varenicline tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9e295f42-88f3-5dda-2358-f57b5d71735c [6]DailyMed - VARENICLINE tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=78d1857f-8708-5410-792f-4a3e5e7971a5 [7]DailyMed - ALPRAZOLAM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d9b0e228-17cf-40d7-b62e-5050311c571c DailyMed - ALPRAZOLAM EXTENDED RELEASE- alprazolam tablet, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a64496be-bf43-4ba9-a4b1-bd632965c1a0 DailyMed - ALPRAZOLAM solution, concentrate (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b945ac6f-796e-41ef-85e9-61007e4a4e9a DailyMed - ALPRAZOLAM tablet, orally disintegrating (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5ceed721-2e65-4c81-bd84-f110b1ac9d2e [8]DailyMed - CHLORDIAZEPOXIDE HCL AND CLIDINIUM BROMIDE- chlordiazepoxide hcl and clidinium bromide capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cd820fcb-b6a8-43f4-a6d9-f94546d380c8 [9]DailyMed - CLONAZEPAM tablet, orally disintegrating (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cb2e209e-e69b-422b-8abb-34df2bc92caa DailyMed - CLONAZEPAM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ebc11109-e7bf-452d-b675-4b3236d54164 [10]DailyMed - CLORAZEPATE DIPOTASSIUM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a4b80e69-b7c7-471a-8ce8-4e992808c669 [11]DailyMed - DIAZEPAM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c397a9da-862f-4f3f-8109-7d21691de53a

	DailyMed - DIAZEPAM- diazepam oral solution DIAZEPAM (diazepam oral solution- concentrate solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cdb839fb-27e5-4a11-aed6-da0a7ab6e996 DailyMed - DIAZEPAM INTENSOL solution, concentrate (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1aaf9375-ae3d-4fed-9cd1-24102e00be1a [12]DailyMed - LORAZEPAM concentrate (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=73bfaeab-94db-48c2-a194-8b173025de78 DailyMed - LORAZEPAM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4fae1607-69d7-47ce-9b78-7474af50036d [13]DailyMed - OXAZEPAM capsule, gelatin coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a0d5a4c1-ec79-42e6-8e8f-ae4d144edb43 [14]DailyMed - ESTAZOLAM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a1e3b4bf-22e9-430a-a768-4d86ae886c9e [15]DailyMed - ESZOPICLONE tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0b363b90-93dc-1fc1-0501-d140dfc762c7 [16]DailyMed - FLURAZEPAM HYDROCHLORIDE capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8f476891-1346-4e8c-ac1b-f8cbdc64f5a1 [18]DailyMed - RAMELTEON tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b71cd925-1bae-5a6a-072b-941ad6d3ce65 [19]DailyMed - TEMAZEPAM capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a4370eb4-b00d-4247-af8d-980e59fbbec6 [20]DailyMed - TRIAZOLAM tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5add318e-11b9-42f8-b052-0d8cebb32fcf [21]DailyMed - ZALEPLON capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2f44db39-e1d9-451e-ba31-e4b10366a430

	[22]DailyMed - ZOLPIDEM TARTRATE capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2f1a3600-9bd6-3651-3ab5-1e4e0b0a3916 DailyMed - ZOLPIDEM TARTRATE EXTENDED-RELEASE- zolpidem tartrate tablet, film coated, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2977f646-8a5a-4e7b-94e1-0b0c0c5478ba [23]DailyMed - DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE, AMPHETAMINE SULFATE tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c922de13-7ae0-a09c-e053-2995a90a4411 DailyMed - DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=34726042-2386-4c19-abec-440769fff99a DailyMed - DEXTROAMPHETAMINE solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7658071e-ee2c-4d23-94ce-1906959ec036 [24]DailyMed - ZENZEDI- dextroamphetamine sulfate tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d6394df5-f2c9-47eb-b57e-f3e9cfd94f84 [26]DailyMed - METHAMPHETAMINE HYDROCHLORIDE tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=90c02ac6-e5e2-4c97-8c68-81e4e389a195 [27]DailyMed - DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE, AMPHETAMINE SULFATE tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c922de13-7ae0-a09c-e053-2995a90a4411 [29]DailyMed - ATOMOXETINE- atomoxetine capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f266ab7b-5a68-42b5-b204-e3249bea0aed [30]DailyMed-DEXMETHYLPHENIDATEHYDROCHLORIDEcapsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5312f2c3-bd73-4d29-b8d1-e989282be750

	DailyMed - DEXMETHYLPHENIDATE HYDROCHLORIDE tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=830df993-db01-40df-beef-90af6b86f561 [31]DailyMed - METHYLPHENIDATE capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1f8983ce-71b8-4c62-830d-e4692ddededa DailyMed - METHYLPHENIDATE HCL solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7d66dbf9-3966-4949-b7c9-d2ca8c7f3278 DailyMed - METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE- methylphenidate hydrochloride tablet, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b1b0f2ff-d9df-42ab-b471-226ecf97e075 DailyMed - METHYLPHENIDATE HYDROCHLORIDE tablet, chewable (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bb73cd3e-aa7c-4f7e-826d-75e71fb6d1e0 DailyMed - METHYLPHENIDATE HYDROCHLORIDE tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f04e8194-7077-42cf-99ee-b61e42a76cf0 [32]DailyMed - AMPHETAMINE SULFATE- amphetamine sulfate tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=26dbad66-13c4-4906-88b3-ab7ee191466c [33]DailyMed - DYANAVEL XR- amphetamine suspension, extended release DYANAVEL XR- amphetamine tablet, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ae304b29-0b40-40ec-ad0d-76b742d4a9b9 [34]DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a [35]DailyMed-METHYLPHENIDATE HYDROCHLORIDE CD- methylphenidate hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e45c75dc-d381-475b-b649-a871c8a36e60 [36]DailyMed-QUILLIVANTXR-methylphenidatehydrochloride suspension, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c2dc2109-44a6-4797-b04e-18761dd9d45a

	[37]DailyMed - QUILLICHEW ER- methylphenidate hydrochloride tablet, chewable, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=defc1205-8e90-4b1e-b862-05e4c35c7364 [38]DailyMed-AZSTARYS-serdexmethylphenidateand dexmethylphenidate capsule (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=00b5e716-5564-4bbd-acaf-df2bc45a5663
Standard Opt-Out Formulary – 2021	**MIA Analysis**

• 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.	1. **Tier 1**: 66.2% of all MH medications with QL versus 32% of all M/S medications with QL 2. **Tier 3**: 23.1% of all MH medications and 45.5% of all SUD medications with QL versus 8.8% of all M/S medications with QL As above in the ACF formulary, the SUD category represents a very small number of drugs, most of which are used to treat tobacco use and opioid use disorders. Three of the 4 SUD drugs with QL on Tier 1 (buprenorphine sl tab[1], buprenorphine/naloxone sl tab and film[2]) are also opioids themselves, and have a significant potential for abuse or misuse, indicating the need for close monitoring. Three of the 5 SUD drugs with QL on Tier 3 (Nicotrol nasal spray[3], Nicotrol inhaler[4] and Apo-varenicline[5]) are used to treat tobacco use disorder, and two are used in the treatment of opioid use disorder (Lucemyra[39] and Kloxxado[40]). Quantity limits have been placed on these drugs to align with treatment guidelines, as well as FDA dosing recommendations. These limits reflect the factors of enhance patient safety, discourage misuse, waste and abuse, and cost-effectiveness, making it appropriate to apply QL. In the MH category, the antianxiety class also contains controlled substances with potential for misuse and abuse (**Antianxiety agents with QL on Tier 1**: alprazolam (3 dosage forms)[7], chlordiazepoxide[8], clonazepam tabs and ODT[9], clorazepate[10], diazepam (3 dosage forms)[11], lorazepam tabs and oral concentrate[12], oxazepam[13]. **Antianxiety agents with QL on Tier 1**: alprazolam (2 dosage forms)[7] Hypnotics is another class that contains controlled substances and chronic use of these agents for sleep disorders may actually be a sign of underlying physical or psychiatric disorders, it is important to monitor their use in order to assess the need for further evaluation of the condition. **Hypnotics with QL on Tier 1**: estazolam[14], eszopiclone[15], flurazepam[16], ramelteon[18], temazepam[19], triazolam[20], zaleplon[21], zolpidem tabs[22]. **Hypnotics with QL on Tier 3**: zolpidem ER tabs[22]). Most of the drugs used to treat ADHD are schedule II-controlled substances, which have the highest potential for abuse among FDA approved prescription drugs. (**ADHD agents with QL on Tier 1**: dextroamphetamine (3 dosage forms)[23], Zenzedi[24], methamphetamine[26], amphetamine/dextroamphetamine[27], atomoxetine[29], dexmethylphenidate (4 dosage forms)[30], methylphenidate (5 dosage forms)[31], (**ADHD agents with QL on Tier 3:** amphetamine[32], Dyanavel XR[33], Qelbree[34], methylphenidate CR tabs, chew tabs[35], Quillivant XR[36], Quillichew ER[37], Azstarys[38]). Quantity limits have been placed on these drugs to align with treatment guidelines, as well as FDA dosing recommendations. These limits also reflect the factors of enhance patient safety, discourage misuse, waste and abuse, and cost-effectiveness, making it appropriate to apply QL. [39]DailyMed - LUCEMYRA- lofexidine hydrochloride tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b748f308-ba71-4fd9-84ec-ec7e0f210885

	[40]DailyMed - KLOXXADO- naloxone hcl spray (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ebf0f833-c1c0-487c-8f29-01fa8c61b6cb

Standard Opt-Out Formulary 2021 Plan – Aetna

Pharmacy Prior Authorization (PA) for Standard Opt-Out Formulary 2021 Plan – Aetna

PRIOR AUTHORIZATION (PA) ANALYSIS							
Plan: State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021							
Category		Analysis					
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	TOTAL Drug Count by Tier	1,162	269	636	212	188	2,467
	PA Drug Count by Tier	74	16	21	207	172	490
	% of Total PA Drugs by Tier	15.1%	3.3%	4.3%	42.2%	35.1%	
	% MED/SURG Drugs with PA	6.4%	5.9%	3.3%	97.6%	91.5%	**19.9%**
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	135	17	36	0	6	194
	PA Drug Count by Tier	0	0	0	0	6	6
	% of Total PA Drugs by Tier	0.0%	0.0%	0.0%	0.0%	100.0%	
	% MH Drugs with PA	0.0%	0.0%	0.0%	0.0%	100.0%	**3.1%**
Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
	Total Drug Count by Tier	10	1	5	1	1	18
	PA Drug Count by Tier	0	0	1	0	0	1

	% of Total PA Drugs by Tier	0.0%	0.0%	100.0%	0.0%	0.0%	
	% SUD Drugs with PA	0.0%	0.0%	20.0%	0.0%	0.0%	**5.6%**

* 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:

- 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:

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MH/SUD DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTIANXIETY		22	0	0%
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-approved indications, clinical use, and guidelines documents	65	2	3%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MH/SUD DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
HYPNOTICS Hetlioz caps, oral susp	> Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use	15	2	13%
ADHD		37	0	0%
SUD Lucemyra	> Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use > Requirement for additional treatment supportive therapies	18	1	6%

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:

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
ANTIVIRALS - HEPATITIS C	> Appropriate medication uses based on national guidelines > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	14	11	79%
ANTINEOPLASTIC & ADJUNCTIVE THERAPIES	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	144	107	74%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
OSTEOPOROSIS AGENTS	> Patient safety concerns exist/Unknown long-term safety or durability > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents	16	8	50%
GROWTH HORMONE	> Appropriate medication uses based on national guidelines > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations > Limited to a specific population based on FDA-approved indications, clinical use, and guidelines documents > Potential for inappropriate, off-label use	3	3	100%
ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	> Patient safety concerns exist/Unknown long-term safety or durability > Treatment based on obtaining applicable lab values or test results > Use in appropriate patient populations	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%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH PA	**Prior Authorization Factors**	**TOTAL Drug Count**	**Count of Drugs with PA**	**Percent of Drugs with PA**
DERM - ANTIPSORIATICS	> Patient safety concerns exist/Unknown long-term safety or durability > Use in appropriate patient populations	20	12	60%
DERM - IMMUNOSUPPRESSANTS	> Appropriate medication uses based on national guidelines > Use in appropriate patient populations	2	2	100%

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

Step Therapy (ST) for Standard Opt-Out Formulary 2021 Plan – Aetna

STEP THERAPY ANALYSIS							
Plan: State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021							
Category		**Analysis**					
Medical / Surgical	**Medical / Surgical**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	1,162	269	636	212	188	2,467
	ST Drug Count by Tier	0	9	27	0	0	36
	% of Total ST Drugs by Tier	0.0%	25.0%	75.0%	0.0%	0.0%	
	% MED/SURG Drugs with ST	0.0%	3.3%	4.2%	0.0%	0.0%	**1.5%**
Mental Health	**Mental Health**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	135	17	36	0	6	194
	ST Drug Count by Tier	0	9	3	0	0	12
	% of Total ST Drugs by Tier	0.0%	75.0%	25.0%	0.0%	0.0%	

	% MH Drugs with ST	0.0%	52.9%	8.3%	0.0%	0.0%	**6.2%**
Substance Use Disorder	**Substance Use Disorder**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	10	1	5	1	1	18
	ST Drug Count by Tier	0	0	0	0	0	0
	% of Total ST Drugs by Tier	0.0%	0.0%	0.0%	0.0%	0.0%	
	% SUD Drugs with ST	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**

* 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:

- 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:

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MH/SUD DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIANXIETY		22	0	0%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MH/SUD DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
ANTIDEPRESSANTS Fetzima cap/Pack Pexeva Trintellix Viibryd tab/Pack	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	55	6	11%
ANTIPSYCHOTICS Latuda Rexulti Vraylar cap/Pack	> 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	65	4	6%
HYPNOTICS Belsomra Edluar	> 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	15	2	13%
ADHD		37	0	0%
SUD		18	0	0%

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

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

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
OSTEOPOROSIS AGENTS	> Promote use of most cost-effective products (generics and/or lower cost brands) > Alternatives available in the drug class (including generics) used to treat the same condition	16	2	13%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
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%
GI 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%
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%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH ST	**Step Therapy Factors**	**TOTAL Drug Count**	**Count of Drugs with ST**	**Percent of Drugs with ST**
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

QUANTITY LIMITS (QL) ANALYSIS							
Plan: State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021							
Category		**Analysis**					
Medical / Surgical	**Medical / Surgical**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	1,162	269	636	212	188	2,467
	QL Drug Count by Tier	223	40	61	202	171	697
	% of Total QL Drugs by Tier	32.0%	5.7%	8.8%	29.0%	24.5%	
	% MED/SURG Drugs with QL	19.2%	14.9%	9.6%	95.3%	91.0%	**28.3%**
Mental Health	**Mental Health**	**Tier 1**	**Tier 2**	**Tier 3**	**Tier 4**	**Tier 5**	**Total Drugs**
	Total Drug Count by Tier	135	17	36	0	6	194
	QL Drug Count by Tier	43	3	15	0	4	65
	% of Total QL Drugs by Tier	66.2%	4.6%	23.1%	0.0%	6.2%	
	% MH Drugs with QL	31.9%	17.6%	41.7%	0.0%	66.7%	**33.5%**

	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs
Substance Use Disorder	Total Drug Count by Tier	10	1	5	1	1	18
	QL Drug Count by Tier	4	1	5	0	1	11
	% of Total QL Drugs by Tier	36.4%	9.1%	45.5%	0.0%	9.1%	
	% SUD Drugs with QL	40.0%	100.0%	100.0%	0.0%	100.0%	**61.1%**

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

Comparative Analysis for Quantity Limits 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 with QL**	**Percent of Drugs with QL**
ANTIANXIETY Alprazolam tabs, ER tabs, 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	17	77%
ANTIDEPRESSANTS		55	0	0%
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)	65	2	3%
HYPNOTICS Estazolam Eszopiclone Flurazepam Hetlioz caps, oral susp Ramelteon Temazepam Triazolam Zaleplon Zolpidem tab, ER tab	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	15	11	73%

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 with QL**	**Percent of Drugs with QL**
ADHD Includes substance controlled drugs used to treat ADHD.	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	37	35	95%
SUD Apo-Varenicline Bupropion ER Nicotrol Oral Inhaler Nicotrol Nasal Spray Buprenorphine SL, Film Buprenorphine/Naloxone Zubsolv Kloxxado nasal Lucemyra Vivitrol inj	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS) > Discourage misuse/waste through dose efficiency QLs (ensure appropriate strength is utilized) (COST-EFFECTIVENESS) > Lack of documented efficacy at higher doses (COST-EFFECTIVENESS) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	18	11	61%

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

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

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
ANTIVIRALS - HIV	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	60	60	100%
ANTIVIRALS - HEPATITIS C	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	14	14	100%
ANTINEOPLASTICS AND ADJUNCTIVE THERAPIES	> 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) > Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized) > Lack of documented efficacy at higher doses	144	107	74%
GROWTH HORMONE	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY) > Prevent overutilization (COST-EFFECTIVENESS)	3	3	100%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
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	12	100%
ANTIEMETICS - 5-HT3	> Potential to be prescribed in greater qty and/or higher dose than safe and effective per FDA (PT SAFETY) > Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY)	9	9	100%
MULTIPLE SCLEROSIS AGENTS	> Promote appropriate dosing, including strength/frequency (PT SAFETY) > Prevent overutilization (PT SAFETY) > Possible abuse or misuse by the patient (PT SAFETY)	20	20	100%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
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) > Maximum daily dose/duration of use limits (DISCOURAGE MISUSE/ABUSE)	10	8	80%

State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021				
MED/SURG DRUG CLASSES WITH QL	**Quantity Limit Factors**	**TOTAL Drug Count**	**Count of Drugs with QL**	**Percent of Drugs with QL**
IMMUNOSUPPRESSANTS	> 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) > Discourage misuse and waste through dose efficiency QLs (ensure appropriate strength is utilized) > Lack of documented efficacy at higher doses	18	16	89%

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

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

The methodology used in the analysis included comparing the percent of PA, ST, QL at the drug class level in order to achieve a more focused and appropriate comparison. The results include of ALL of the MH/SUD classes since they are the focus of the analysis, and it is important to see how each NQTL affects all of those classes. Comparable MED/SURG classes, as defined by clinical pharmacists doing the analysis, are those that treat conditions that require long-term therapy and have a similar or greater magnitude of the NQTL as seen in the MH/SUD classes, as opposed to classes that are categorized as M/S but are actually made up of other items as described above.

As described above, comparable M/S classes, are those that treat conditions that require long-term therapy and have a similar or greater magnitude of the NQTL as seen in the MH/SUD classes. MH/SUD classes remain the same for each NQTL because they are the only classes in that category. It would not be practical to include each and every M/S drug class in the results (as is done in the MH/SUD classes) due to the volume of drugs and classes in that category, so only a sample of classes are shown. The comparable M/S classes are not the same in each NQTL because the classes that are listed for PA, for example, may not be appropriate for ST due to the make-up of drugs that are available in the class, the conditions

they treat, and the factors. For example, on the ACF formulary, 16% of the Antipsychotics class has PA but there is no ST in the class. The drugs requiring PA are brands that did not have a generic available in 2021 and are indicated for use in specific populations or as adjunct therapy. Prior authorization is appropriate for these drugs to ensure they are being used for the right patients in the right situations but requiring a trial of previous therapy is less applicable in this class. Similarly, the M/S class of Antineoplastics has PA on 76% of the drugs, since it is important to ensure the right drug for the right patient and situation, but there is no ST in the class since that approach is not appropriate in cancer treatment.

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

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

An analysis of the formulary data showed that the M/S category had a higher percentage of drugs requiring PA than MH or SUD for both ACF and SOO formularies, as below:

Drugs requiring PA – Advanced Control Formulary – 2021

- 35.4% (840 out of 2,373) of the drugs in the M/S category
- 9.8% (17 out of 173) of the drugs in the MH category
- None of the drugs in the SUD category

Drugs requiring PA – Standard Opt Out Formulary – 2021

- 19.9% (490 out of 2,467) of the drugs in the M/S category
- 3.1% (6 out of 194) of the drugs in the MH category
- 5.6% (1 out of 18) of the drugs in the SUD category

The analysis by the PBM clinician noted that processes of tier placement and UM development are done independently, and one does not rely on or relate to the other. PA is not applied to drugs with the goal of staying above or below a threshold within a given tier. The drugs that have PA were reviewed and the PBM clinician found that it is appropriate for those drugs to require PA based on the factors noted

The written materials analysis revealed that as written factors and standards used for applying ST to drugs are the same and are not used differently or more restrictively based on a drug being for M/S or MH/SUD treatment. The review of the minutes showing the decisions made for the period of 2021-2022 revealed that the decision to apply ST to the M/S drug Qulipta and the MH drug Ambien followed a consistent process.

Also, the analysis of the factors and the level of evidence for the sources used to inform the factors, as written in the policies show a consistent process. The sources of information are not explicit in the minutes but the PBM clinician analyzing the decisions can find the sources and standards as described in the process and assess that the process was followed consistently.

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

Drugs requiring ST – Advanced Control Formulary – 2021

- 1.8% (43 out of 2,373) of the drugs in the M/S category
- 3.5% (6 out of 173) of the drugs in the MH category
- None of the drugs in the SUD category

Drugs requiring ST – Standard Opt Out Formulary – 2021

- 1.5% (36 out of 2,467) of the drugs in the M/S category
- 6.2% (12 out of 194) of the drugs in the MH category
- None of the drugs in the SUD category

While the rate of ST in MH drugs is two times and four times the rate of ST in M/S drugs, in ACF and SOO formularies respectively, these values also represent a *number* of **M/S** drugs with ST that is seven times and three times the number of MH drugs with ST, illustrating that a comparison of percentages alone does not provide a complete view. As noted above, the analysis of the minutes revealed that decisions made to apply ST to M/S and MH/SUD drugs showed a consistent process of applying the factors and utilizing sources with comparable levels of evidence. Also, the analysis by the PBM clinician noted that processes of tier placement and UM development are done independently, and one does not rely on or relate to the other. ST is not applied to drugs with the goal of staying above or below a threshold within a given tier. The drugs that have ST on both formularies were reviewed and the PBM clinician found that it is appropriate for those drugs to require ST based on the factors noted.

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

An analysis of the formulary data showed that quantity limits are applied to the ACF and SOO formularies, as below:

Drugs requiring QL – Advanced Control Formulary – 2021

- 33.0% (783 out of 2,373) of the drugs in the M/S category
- 32.9% (57 out of 173) of the drugs in the MH category
- 57.9% (11 out of 19) of the drugs in the SUD category

Drugs requiring QL – Standard Opt Out Formulary – 2021

- 28.3% (697 out of 2,467) of the drugs in the M/S category
- 33.5% (65 out of 194) of the drugs in the MH category
- 61.1% (11 out of 18) of the drugs in the SUD category
-

The M/S drug category encompasses drugs used to treat specific medical or surgical conditions, as well as **all** other products included in the pharmacy benefit formulary that are not classified as MH or SUD, which may include items such as vaccines, vitamins, insulin syringes and needles, and antibiotics. Since these items are not appropriate comparisons to the drugs that are used to treat anxiety, ADHD, opioid use disorder or tobacco use disorder, for example, but they are still included in the denominator for the M/S category, the rate of QL applying to this category is not a direct reflection of comparable drugs.

Nonetheless, as noted above, the analysis of the minutes revealed that decisions made to apply QL to M/S and MH/SUD drugs showed a consistent process of applying the factors and utilizing sources with comparable levels of evidence. It is important to note that 4 of the 6 MH/SUD classes contain controlled substances (Antianxiety, Hypnotics, ADHD, SUD; ranging from 26%-86% of the class) therefore, a higher percentage of these drugs have QL. In the SUD class, 9 of the 11 drugs with QL are indicated for tobacco use disorder or opioid use disorder where dosing is titrated often, so it is important to monitor the amount used by the patient.

The drugs that have QL on both formularies were reviewed and the PBM clinician found that it is appropriate for those drugs to require QL based on the factors noted. Also, the analysis of the factors and the level of evidence used for the sources used to inform the factors, in operations show a consistent process. No unique process exists that is different in any way to apply the factors; sources used are different and drug/disease-specific. This analysis was done by PBM Clinicians, they are pharmacists, and they made no recommendations regarding NQTLs applied to MH/SUD and M/S drugs. No variation in the use of PBM Clinicians for MH/SUD compared to M/S NQTL analyses.

7. <u>Prescription Drug Formulary Design</u>

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

NQTL's Applicable to Med/Surg Benefits in Prescription Classification	NQTL's Applicable to MH/SUD Benefits in Prescription Classification
Formulary Tiering and Design: Aetna delegates the formulary tiering and design to CVS Caremark. The formulary, also called drug guide, is developed and managed through the activities of CVS Caremark National Pharmacy and Therapeutics (P&T) Committee (P&T Committee) and the Formulary Review Committee (FRC). Formulary decisions are made first as recommendations for additions and deletions voted on by FRC and then these recommendations are forwarded to the P&T Committee for final review and approval. Disciplines, involved in the formulary decision for medications to treat medical, mental health, substance use disorder and medical/surgical conditions included in these committees are pharmacists, physicians, and specialty physicians (allergists, cardiology, endocrinology, family practice, neurology, infectious disease, gerontology, gastroenterology, medical ethics, neurology, psychiatrists, hematology/oncology, pharmacology, and rheumatology). There is no separate formulary for medications to treat medical, mental health, and substance use disorder conditions, and there is no separate process of formulary design for medications to treat medical, mental health, and substance use disorder conditions. Accordingly, there is no mention of a separate formulary for medications to treat medical, mental health, and substance use disorder conditions in the Aetna Health Rider prescription drug plan member information documents. There is no separate committee making decisions only for medications to treat medical, mental health, substance use disorder and medical/surgical conditions. The P&T Committee reviews medications from a purely clinical perspective and does not have access to nor does it consider any information on rebates, negotiated discounts or net costs. FRC makes business recommendations evaluating factors such as utilization trends, impact of generic drugs or drugs designated to become available over the counter, brand sand generic pipeline, line of business, plan sponsor cost, applicable manufacturer agreement, potential impact on	**Formulary Tiering and Design:** **In effect since 1/1/2020 Aetna added coverage state specific benefit code to bypass formulary exclusions for drugs on the "Medication Assisted Therapy " list to meet the ASAM criteria.** Aetna delegates the formulary tiering and design to CVS Caremark. The formulary, also called drug guide, is developed and managed through the activities of CVS Caremark National Pharmacy and Therapeutics (P&T) Committee (P&T Committee) and the Formulary Review Committee (FRC). Formulary decisions are made first as recommendations for additions and deletions voted on by FRC and then these recommendations are forwarded to the P&T Committee for final review and approval. Disciplines, involved in the formulary decision for medications to treat medical, mental health, substance use disorder and medical/surgical conditions included in these committees are pharmacists, physicians, and specialty physicians (allergists, cardiology, endocrinology, family practice, neurology, infectious disease, gerontology, gastroenterology, medical ethics, neurology, psychiatrists, hematology/oncology, pharmacology, and rheumatology). There is no separate formulary for medications to treat medical, mental health, and substance use disorder conditions, and there is no separate process of formulary design for medications to treat medical, mental health, and substance use disorder conditions. Accordingly, there is no mention of a separate formulary for medications to treat medical, mental health, and substance use disorder conditions in the Aetna Health Rider prescription drug plan member information documents. There is no separate committee making decisions only for medications to treat medical, mental health, substance use disorder and medical/surgical conditions. The P&T Committee reviews medications from a purely clinical perspective and does not have access to nor does it consider any information on rebates, negotiated discounts or net costs. FRC makes business recommendations evaluating factors such as utilization

members. CVS Caremark works to include the most cost-effective drugs on the drug list. The above processes are used when making formulary decisions for all drug classes including drugs used for MH/SUD and MED/SURG conditions. **Cost-control measures:** When drug classes have multiple generic and low-cost brand-name options that cover the same indications as more costly brand-name options in the same class, and the generic and low-cost brand-name options offer similar efficacy and safety. **Therapeutic alternatives** in formulary design: since many brand-name drugs do not provide clear clinical and/or financial advantages when compared to available drug options within the therapeutic class, several strategies are available to promote cost-effective use of medications ranging from tiered copays, excluding products from coverage or having a closed plan design. • Tiered copays encourage members to use preferred formulary drugs. • Products not included in the formulary have therapeutic alternatives available that deliver cost savings and are covered in the formulary. Plan Language Coverage and exclusions Providing covered services Your prescription drug plan provides covered services. Your provider can give you a prescription in different ways including: • A written prescription that you take to a network pharmacy • Calling or e-mailing a prescription to a network pharmacy • Submitting the prescription to a network pharmacy electronically For covered pharmacy services: • You need a prescription from the prescribing provider	trends, impact of generic drugs or drugs designated to become available over the counter, brand sand generic pipeline, line of business, plan sponsor cost, applicable manufacturer agreement, potential impact on members. CVS Caremark works to include the most cost-effective drugs on the drug list. The above processes are used when making formulary decisions for all drug classes including drugs used for MH/SUD and MED/SURG conditions. **Cost-control measures:** When drug classes have multiple generic and low-cost brand-name options that cover the same indications as more costly brand-name options in the same class, and the generic and low-cost brand-name options offer similar efficacy and safety. **Therapeutic alternatives** in formulary design: since many brand-name drugs do not provide clear clinical and/or financial advantages when compared to available drug options within the therapeutic class, several strategies are available to promote cost-effective use of medications ranging from tiered copays, excluding products from coverage or having a closed plan design. • Tiered copays encourage members to use preferred formulary drugs. • Products not included in the formulary have therapeutic alternatives available that deliver cost savings and are covered in the formulary. Plan Language Coverage and exclusions Providing covered services Your prescription drug plan provides covered services. Your provider can give you a prescription in different ways including: • A written prescription that you take to a network pharmacy • Calling or e-mailing a prescription to a network pharmacy • Submitting the prescription to a network pharmacy electronically

• You need to show your ID card to the network pharmacy when you get a prescription filled **Off-label use** Off-label drug use unless recognized for treatment in any of the standard reference compendia or for indications recognized through peer-reviewed medical literature, and includes medically necessary services associated with the administration of the recognized drug Prescription drugs: - That are ordered by a dentist or prescribed by an oral surgeon in relation to the removal of teeth or prescription drugs for the treatment to a dental condition - That are considered oral dental preparations and fluoride rinses except pediatric fluoride tablets or drops as specified on the plan's drug guide - That are being used or abused in a manner that is determined to be furthering an addiction to a habit-forming substance, the use of or intended use of which is illegal, unethical, imprudent, abusive, not medically necessary or otherwise improper and drugs obtained for use by anyone other than the member as identified on the ID card • Replacement of lost or stolen prescriptions • Test agents except diabetic test agents • Treatment, drug, service or supply to stop or reduce smoking or the use of tobacco products or to treat or reduce nicotine addition, dependence or craving including medications, nicotine patches and gum unless approved by the FDA as an aid to stop the use of tobacco products • [We reserve the right to exclude: - A manufacturer's product when the same or similar drug (one with the same active ingredient or same therapeutic effect), supply or equipment is on the plan's drug guide	For covered pharmacy services: • You need a prescription from the prescribing provider • You need to show your ID card to the network pharmacy when you get a prescription filled **Off-label use** Off-label drug use unless recognized for treatment in any of the standard reference compendia or for indications recognized through peer-reviewed medical literature, and includes medically necessary services associated with the administration of the recognized drug Prescription drugs: - That are ordered by a dentist or prescribed by an oral surgeon in relation to the removal of teeth or prescription drugs for the treatment to a dental condition - That are considered oral dental preparations and fluoride rinses except pediatric fluoride tablets or drops as specified on the plan's drug guide - That are being used or abused in a manner that is determined to be furthering an addiction to a habit-forming substance, the use of or intended use of which is illegal, unethical, imprudent, abusive, not medically necessary or otherwise improper and drugs obtained for use by anyone other than the member as identified on the ID card • Replacement of lost or stolen prescriptions • Test agents except diabetic test agents • Treatment, drug, service or supply to stop or reduce smoking or the use of tobacco products or to treat or reduce nicotine addition, dependence or craving including medications, nicotine patches and gum unless approved by the FDA as an aid to stop the use of tobacco products • [We reserve the right to exclude:

- Any dosage or form of a drug when the same drug is available in a different dosage or form on the plan's drug guide] There is no separate specialty pharmacy formulary and "non-specialty" formulary. There are not four formularies. This information is about two formularies, Advanced Control Formulary and Standard Opt Out. Both formularies have drugs that are specialty and drugs that are not specialty. On page 9 of the Aetna Health Rider prescription drug plan, there is member information about what is needed to know about the prescription drug plan such as: · How to access network pharmacies · How to get an emergency **prescription** filled · Coverage and exclusions · How to access their benefit · Where their schedule of benefits fits in · **Precertification** requirements that apply · Utilization review · Requesting a medical exception · General provisions – other things you should know · How to read your schedule of benefits It also states: "This plan doesn't cover all **prescription** drugs and some coverage may be limited. This doesn't mean you can't get **prescription** drugs that aren't covered; you can, but you have to pay for them yourself." On page 9 of the Aetna Health Rider prescription drug plan, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide; members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received.	- A manufacturer's product when the same or similar drug (one with the same active ingredient or same therapeutic effect), supply or equipment is on the plan's drug guide - Any dosage or form of a drug when the same drug is available in a different dosage or form on the plan's drug guide] There is no separate specialty pharmacy formulary and "non-specialty" formulary. There are not four formularies. This information is about two formularies, Advanced Control Formulary and Standard Opt Out. Both formularies have drugs that are specialty and drugs that are not specialty. On page 9 of the Aetna Health Rider prescription drug plan, there is member information about what is needed to know about the prescription drug plan such as: · How to access network pharmacies · How to get an emergency **prescription** filled · Coverage and exclusions · How to access their benefit · Where their schedule of benefits fits in · **Precertification** requirements that apply · Utilization review · Requesting a medical exception · General provisions – other things you should know · How to read your schedule of benefits It also states: "This plan doesn't cover all **prescription** drugs and some coverage may be limited. This doesn't mean you can't get **prescription** drugs that aren't covered; you can, but you have to pay for them yourself." On page 9 of the Aetna Health Rider prescription drug plan, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide; members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received.

All formularies include generic drugs, which are in the lowest copay tier for members. Brand-name products may be considered preferred or non-preferred in the common three-tier plan design. Preferred brand-name drugs are encouraged with a lower copay than non-preferred brand-name products. Tiered benefit design encourages generic utilization and lower pharmacy cost through copay differentials. The goal is to include in the formulary the lowest net cost drug within each therapeutic class while ensuring that options available on the formularies are consistent with current standards of practice and clinical guidelines. Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates factors that may affect the formulary. The FRC makes business recommendations based on such factors to the P&T Committee. It is important to note that any drug product must first be deemed safe and effective by the P&T Committee before it is considered eligible for inclusion on a CVS Caremark Formulary or Drug List, and that any recommendations made by the FRC must be approved by the P&T Committee before implementation. The P&T Committee reviews all standard formularies annually. The review is conducted by drug class to assure that the formulary recommendations previously established are maintained and to recommend additional changes for clinical appropriateness if advisable based on newly available pharmaceutical information. Formulary benefit design and copay tiering are applied consistently across all drugs and drug classes and do not discriminate based on whether the drug is for a medical or surgical condition, mental health or substance use disorder diagnosis, or other health conditions. Any pharmacy coverage factors, sources or evidentiary standards, processes and development or implementation strategies applied to drugs used to treat mental health or substance use disorders are comparable to, and are applied no more stringently than the coverage factors, source or evidentiary standards, processes and development or implementation	All formularies include generic drugs, which are in the lowest copay tier for members. Brand-name products may be considered preferred or non-preferred in the common three-tier plan design. Preferred brand-name drugs are encouraged with a lower copay than non-preferred brand-name products. Tiered benefit design encourages generic utilization and lower pharmacy cost through copay differentials. The goal is to include in the formulary the lowest net cost drug within each therapeutic class while ensuring that options available on the formularies are consistent with current standards of practice and clinical guidelines. Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates factors that may affect the formulary. The FRC makes business recommendations based on such factors to the P&T Committee. It is important to note that any drug product must first be deemed safe and effective by the P&T Committee before it is considered eligible for inclusion on a CVS Caremark Formulary or Drug List, and that any recommendations made by the FRC must be approved by the P&T Committee before implementation. The P&T Committee reviews all standard formularies annually. The review is conducted by drug class to assure that the formulary recommendations previously established are maintained and to recommend additional changes for clinical appropriateness if advisable based on newly available pharmaceutical information. Formulary benefit design and copay tiering are applied consistently across all drugs and drug classes and do not discriminate based on whether the drug is for a medical or surgical condition, mental health or substance use disorder diagnosis, or other health conditions. Any pharmacy coverage factors, sources or evidentiary standards, processes and development or implementation strategies applied to drugs used to treat mental health or substance use disorders are comparable to, and are applied no more stringently than the coverage

strategies used in applying the limitations to drugs used to treat medical or surgical conditions. The formulary tiers are based on whether the drug is available as a generic or a brand product, and whether the brand or generic drug product is considered preferred or non-preferred. Plan Language **Brand-name prescription drug** An FDA approved **prescription drug** marketed with a specific brand name by the company that manufactures it, usually by the company which develops and patents it. **Generic prescription drug, generic drug** A **prescription drug** with the same dosage, safety, strength, quality, performance and intended use as the brand name product. It is defined as therapeutically equivalent by the U.S. Food and Drug Administration (FDA) and is considered to be as effective as the brand name product. **Non-preferred drug** A **prescription drug** or device that may have a higher out-of-pocket cost than a **preferred drug**. **Preferred drug** A **prescription drug** or device that may have a lower out-of-pocket cost than a **non-preferred drug**. On page 7 of the Aetna Health Rider prescription drug plan explains this formulary design for members using the words “drug guide” and explains how to access this pharmacy benefit, including retail, mail	factors, source or evidentiary standards, processes and development or implementation strategies used in applying the limitations to drugs used to treat medical or surgical conditions. The formulary tiers are based on whether the drug is available as a generic or a brand product, and whether the brand or generic drug product is considered preferred or non-preferred. Plan Language **Brand-name prescription drug** An FDA approved **prescription drug** marketed with a specific brand name by the company that manufactures it, usually by the company which develops and patents it. **Generic prescription drug, generic drug** A **prescription drug** with the same dosage, safety, strength, quality, performance and intended use as the brand name product. It is defined as therapeutically equivalent by the U.S. Food and Drug Administration (FDA) and is considered to be as effective as the brand name product. **Non-preferred drug** A **prescription drug** or device that may have a higher out-of-pocket cost than a **preferred drug**. **Preferred drug** A **prescription drug** or device that may have a lower out-of-pocket cost than a **non-preferred drug**. On page 7 of the Aetna Health Rider prescription drug plan explains this formulary design for members using the words “drug guide” and explains how to access this pharmacy benefit, including retail, mail

order, and specialty pharmacies, including 90 day supply for maintenance drugs. On page 9 of the Aetna Health Rider prescription drug plan, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide, members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received. On page 13 of the Aetna Health Rider prescription drug plan COPAY information states: Preferred generic prescription drugs 30 day supply at a retail pharmacy $15 after deductible 31-90 day supply at a retail pharmacy or mail order $30 after deductible Value prescription drugs 30 day supply at retail pharmacy $3 after deductible 31-90 day supply at retail or mail order pharmacy $6 after deductible Preferred brand name prescription drugs 30 day supply at retail pharmacy $35 after deductible 31-90 day supply at retail or mail order pharmacy $70 after deductible Non-preferred generic prescription drugs 30 day supply at retail pharmacy $85 after deductible 31-90 day supply at retail or mail order pharmacy $170 after deductible Non-preferred brand name prescription drugs 30 day supply at retail pharmacy $85 after deductible 31-90 day supply at retail or mail order pharmacy $170 after deductible Preferred specialty prescription drugs 30 day supply at a specialty pharmacy or retail pharmacy $150 after deductible 31-90 day supply at specialty pharmacy or retail pharmacy $300 after deductible Non-preferred specialty prescription drugs	order, and specialty pharmacies, including 90 day supply for maintenance drugs. On page 9 of the Aetna Health Rider prescription drug plan, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide, members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received. On page 13 of the Aetna Health Rider prescription drug plan COPAY information states: Preferred generic prescription drugs 30 day supply at a retail pharmacy $15 after deductible 31-90 day supply at a retail pharmacy or mail order $30 after deductible Value prescription drugs 30 day supply at retail pharmacy $3 after deductible 31-90 day supply at retail or mail order pharmacy $6 after deductible Preferred brand name prescription drugs 30 day supply at retail pharmacy $35 after deductible 31-90 day supply at retail or mail order pharmacy $70 after deductible Non-preferred generic prescription drugs 30 day supply at retail pharmacy $85 after deductible 31-90 day supply at retail or mail order pharmacy $170 after deductible Non-preferred brand name prescription drugs 30 day supply at retail pharmacy $85 after deductible 31-90 day supply at retail or mail order pharmacy $170 after deductible Preferred specialty prescription drugs 30 day supply at a specialty pharmacy or retail pharmacy $150 after deductible 31-90 day supply at specialty pharmacy or retail pharmacy $300 after deductible

30 day supply at a specialty pharmacy or retail pharmacy $150 after deductible 31-90 day supply at specialty pharmacy or retail pharmacy $300 after deductible • **Maximum copay is capped at $150** On page 11 of the Aetna Health Rider prescription drug plan, information on deductible and cost share waiver for tobacco cessation prescription and OTC drugs. The prescription drug and the per prescription cost share will not apply to the first two 90-day treatment programs for tobacco cessation prescription and OTC drugs when obtained at a network retail pharmacy. This means they will be paid at 100%. Member's per prescription cost share will apply after those two programs have been exhausted. Deductible waiver provisions for preventive prescription drugs and supplements information indicate that the deductible is waived for all preferred and non-preferred generic, value and brand name prescription drugs. No deductible apply to preventive covered prescription drug expenses for those prescription drugs used to treat: The prevention of conditions relating to: • Hypertension • Heart disease • Diabetic complications • Asthmatic episodes • Conditions resulting from osteoporosis • Stroke • Various pediatric conditions including maternal and fetal problems during pregnancy Plan Language Tobacco cessation prescription and OTC drugs Covered services include FDA approved prescription and OTC drugs to help stop the use of tobacco products. You must receive a prescription from your provider and submit the prescription to the pharmacy for processing. It also includes two 90-day courses of	Non-preferred specialty prescription drugs 30 day supply at a specialty pharmacy or retail pharmacy $150 after deductible 31-90 day supply at specialty pharmacy or retail pharmacy $300 after deductible Maximum **copay is capped at $150** On page 11 of the Aetna Health Rider prescription drug plan, information on deductible and cost share waiver for tobacco cessation prescription and OTC drugs. The prescription drug and the per prescription cost share will not apply to the first two 90-day treatment programs for tobacco cessation prescription and OTC drugs when obtained at a network retail pharmacy. This means they will be paid at 100%. Member's per prescription cost share will apply after those two programs have been exhausted. Deductible waiver provisions for preventive prescription drugs and supplements information indicate that the deductible is waived for all preferred and non-preferred generic, value and brand name prescription drugs. No deductible apply to preventive covered prescription drug expenses for those prescription drugs used to treat: The prevention of conditions relating to: • Hypertension • Heart disease • Diabetic complications • Asthmatic episodes • Conditions resulting from osteoporosis • Stroke • Various pediatric conditions including maternal and fetal problems during pregnancy Plan Language Tobacco cessation prescription and OTC drugs Covered services include FDA approved prescription and OTC drugs to help stop the use of tobacco products. You must receive a prescription from your provider and submit the prescription to the

nicotine replacement therapy during each [contract] year. See the Deductible and cost share waiver for tobacco cessation prescription and OTC drugs provision for more information. Over-the-counter drugs Covered services include certain OTC medications, as determined by the plan. Coverage of these medications may require a prescription. You can access a list of these OTC medications. See the Contact us section for how. [Note: This will print for plans subject to ACA and plans not subject to ACA but elect to include this benefit.] [Preventive care drugs and supplements Covered services include preventive care drugs and supplements, including OTC drugs and supplements, as required by the ACA.] **Specialty Drug designation:** Specialty pharmacy member information indicates that members can get many commonly prescribed specialty medicines from a specialty pharmacy, or based on their plan, they can use a retail pharmacy. Specialty drugs treat complex, chronic conditions. A nurse or pharmacist will often support their use during treatment. These drugs may be injected, infused or taken by mouth. A member may need to refrigerate them. They are often expensive and may not be available at retail pharmacies. Contact information is provided for members to get access to specialty medications. Document is found at: https://www.aetna.com/docfind/cms/assets/pdf/specialty_pharmacy.pdf Aetna delegates the Specialty Drug designation to CVS Caremark, except for the purpose of applying a copay or restricting distribution at a specialty pharmacy. The CVS Caremark specialty drug designation decision making process details include the specialty drug designation decisions are made by CVS Caremark Pharmaceutical Technology Evaluation Committee (PTEC). The personnel involved in PTEC is multidisciplinary are voting members making decisions, and is	pharmacy for processing. It also includes two 90-day courses of nicotine replacement therapy during each [contract] year. See the Deductible and cost share waiver for tobacco cessation prescription and OTC drugs provision for more information. Over-the-counter drugs Covered services include certain OTC medications, as determined by the plan. Coverage of these medications may require a prescription. You can access a list of these OTC medications. See the Contact us section for how. [Note: This will print for plans subject to ACA and plans not subject to ACA but elect to include this benefit.] [Preventive care drugs and supplements Covered services include preventive care drugs and supplements, including OTC drugs and supplements, as required by the ACA.] **Specialty Drug designation:** Specialty pharmacy member information indicates that members can get many commonly prescribed specialty medicines from a specialty pharmacy, or based on their plan, they can use a retail pharmacy. Specialty drugs treat complex, chronic conditions. A nurse or pharmacist will often support their use during treatment. These drugs may be injected, infused or taken by mouth. A member may need to refrigerate them. They are often expensive and may not be available at retail pharmacies. Contact information is provided for members to get access to specialty medications. Document is found at: https://www.aetna.com/docfind/cms/assets/pdf/specialty_pharmacy.pdf Aetna delegates the Specialty Drug designation to CVS Caremark, except for the purpose of applying a copay or restricting distribution at a specialty pharmacy. The CVS Caremark specialty drug designation decision making process details include the specialty drug designation

comprised of internal employees' representatives from various business areas including Medical Affairs, Specialty Product Safety, Professional Practice and others. Details of the composition of PTEC personnel include pharmacists, physicians, other businesspersons knowledgeable about the PBM business and pharmacy distribution channels. None of the personnel are MH/SUD specialists. The PTEC committee meets quarterly to evaluate pharmaceuticals, biologics, medical devices and emerging technologies to determine specialty drug designation using an established decision model. CVS Specialty designation and removal decisions are made without regard to whether the drugs are used to treat MH/SUD conditions or MED/SURG conditions and is applied to drugs or drug classes using factors such as risk profile of a drug, safety and effectiveness of drug (e.g., close clinical monitoring), a drug's indication for use and cost, a drug's route of administration or delivery systems, a drug's dispensing requirements (i.e., special handling, special storage). Due to the special handling of the drug or the drug's limited distribution imposed by a manufacturer, the prescription may or may not need to be dispensed from a Specialty Pharmacy. On page 9 of the Aetna Health Rider prescription drug plan, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide; members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received. Coverage requests data for 2021 matched by drug GPI to the drug list was reviewed. Quality control of the data by a PBM pharmacist found that not all requests processed did not match GPI. These non-matching GPIs were also reviewed and are here reported, and are considered to be in-scope since they did not match due to the drug not being present in the drug list. A second PBM pharmacist inspected the data for accuracy. Findings: ACF Totals ACF Totals	decisions are made by CVS Caremark Pharmaceutical Technology Evaluation Committee (PTEC). The personnel involved in PTEC is multidisciplinary are voting members making decisions, and is comprised of internal employees' representatives from various business areas including Medical Affairs, Specialty Product Safety, Professional Practice and others. Details of the composition of PTEC personnel include pharmacists, physicians, other businesspersons knowledgeable about the PBM business and pharmacy distribution channels. None of the personnel are MH/SUD specialists. The PTEC committee meets quarterly to evaluate pharmaceuticals, biologics, medical devices and emerging technologies to determine specialty drug designation using an established decision model. CVS Specialty designation and removal decisions are made without regard to whether the drugs are used to treat MH/SUD conditions or MED/SURG conditions and is applied to drugs or drug classes using factors such as risk profile of a drug, safety and effectiveness of drug (e.g., close clinical monitoring), a drug's indication for use and cost, a drug's route of administration or delivery systems, a drug's dispensing requirements (i.e., special handling, special storage). Due to the special handling of the drug or the drug's limited distribution imposed by a manufacturer, the prescription may or may not need to be dispensed from a Specialty Pharmacy. On page 9 of the Aetna Health Rider prescription drug plan, there is information on how members or their provider can ask for a medical exception for drugs that are not covered in the drug guide if it is medically necessary for a member to use a prescription drug that is not on this drug guide; members or their provider must request a medical exception. The plan will make a coverage decision within 24 hours after an urgent request is received. Coverage requests data for 2021 matched by drug GPI to the drug list was reviewed. Quality control of the data by a PBM pharmacist found that not all requests processed did not match GPI. These non-matching GPIs were also reviewed and are here reported, and are considered to be in-scope since they did not match due to the drug not being present in the drug

		Med/Surg	MH/SUD
1	Number of requests pursuant to § 15-831(c)(1) for coverage of a drug that is not on the formulary	67	10
a	Number of requests in line 1 that were denied as adverse decisions	51	7
b	Number of requests in line 1 that were approved	16	3

- MH/SUD drugs being denied ACF list is:
  - Invega Trinza (paliperidone palmitate ER) (MH)
  - Suboxone 8-2MG SL FILM (SUD)
  - Viibryd (vilazodone) (MH)

The SUD has a generic alternative covered in a preferred tier. The MH drugs have multiple therapeutic alternatives available in preferred tiers.

		SOO Totals	SOO Totals
		Med/Surg	MH/SUD
1	Number of requests pursuant to § 15-831(c)(1) for coverage of a drug that is not on the formulary	10	0
a	Number of requests in line 1 that were denied as adverse decisions	5	0
b	Number of requests in line 1 that were approved	5	0

list. A second PBM pharmacist inspected the data for accuracy. Findings:

		ACF Totals	ACF Totals
		Med/Surg	MH/SUD
1	Number of requests pursuant to § 15-831(c)(1) for coverage of a drug that is not on the formulary	67	10
a	Number of requests in line 1 that were denied as adverse decisions	51	7
b	Number of requests in line 1 that were approved	16	3

- MH/SUD drugs being denied ACF list is:
  - Invega Trinza (paliperidone palmitate ER) (MH)
  - Suboxone 8-2MG SL FILM (SUD)
  - Viibryd (vilazodone) (MH)

The SUD has a generic alternative covered in a preferred tier. The MH drugs have multiple therapeutic alternatives available in preferred tiers.

		SOO Totals	SOO Totals
		Med/Surg	MH/SUD

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- There were no MH/SUD drugs denied.

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

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1	Number of requests pursuant to § 15-831(c)(1) for coverage of a drug that is not on the formulary	10	0
a	Number of requests in line 1 that were denied as adverse decisions	5	0
b	Number of requests in line 1 that were approved	5	0

- There were no MH/SUD drugs denied.

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

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

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

The factors used are:

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

Impact of generic drugs or drugs designated to become available over-the-counter	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm
Brand and generic pipeline	CVS Caremark pipeline reports based on manufacturer information, or manufacturer pipeline information For example: CVS Health Payor Solutions. Drugs to Watch. Drug Pipeline https://payorsolutions.cvshealth.com/tags/drug-pipeline Bristol Myers Squibb Pipeline website https://www.bms.com/researchers-and-partners/in-the-pipeline.html Note: there are thousands of manufacturers, these are just examples.
Line of business	Per regulatory requirement state or federal as applicable
Availability of therapeutic alternatives	Advanced Control Formulary and Standard Opt Out Formulary. Formulary, or drug list drugs used for the disease or condition in question.
Indication for use and cost (cost-effectiveness)	Utilization trends reports Plan sponsor cost reports Applicable manufacturer agreement
Potential impact on members	Advance Control Formulary and Standard Opt Out Formulary. Formulary, or drug list drugs used for the disease or condition in question.

Specialty Drug designation:

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

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

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

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

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

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

Factors	Definitions	Sources	Standard
Brand or generic status of the drug	The FDA definition of a brand drug, and a generic drug.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National	FDA definition of a brand drug, and a generic drug.

		Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	
Impact of generic drugs or drugs designated to become available over-the-counter	The FDA definition of a brand drug, and a generic drug.	1. Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm 2. Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.	FDA definition of a over-the-counter drug, and/or a generic drug.

		https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com 3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm	
Brand and generic pipeline	Drugs that are in late stage development as defined by the pharmaceutical industry	CVS Caremark pipeline reports based on manufacturer information, or manufacturer pipeline information. For Example: CVS Health Payor Solutions. Drugs to Watch. Drug Pipeline https://payorsolutions.cvshealth.com/tags/drug-pipeline Examples of manufacturer's pipeline: https://www.abbvie.com/science/pipeline.html https://www.regeneron.com/pipeline-medicines Note: there are thousands of manufacturers, these are examples	As communicated by drug manufacturers

Line of business	Category of insurance, such as Commercial, Medicare, Health Insurance Marketplace, etc.	Per regulatory requirement state or federal as applicable	Per regulatory requirement state or federal as applicable
Availability of therapeutic alternatives	Alternative drugs available to treat the same condition.	1. Other drugs used for the same disease or condition already in the formularies Advanced Control Formulary and Standard Opt Out. 2. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example: https://www.guidelinecentral.com/guidelines/	Disease/ condition-dependent
Indication for use and cost (cost-effectiveness)	This factor is not considered by the P&T Committee. Cost effectiveness is when multiple drugs exist to treat a given condition, the drugs that are less costly provide more cost-effective therapy. The plan sponsor cost is the net cost option for generic, biosimilar, and brand-name drugs being considered.	Utilization trends reports Plan sponsor cost reports Applicable manufacturer agreement	There is no set threshold, since this is a qualitative comparison. Drug dependent qualitative measure: The cost is a relative measure looking at price of a drug measured in comparison to the price of another drug or group of drugs that are used for the same indication. A cost can be higher than, similar to, or lower than other drugs that are used for the same indication
Potential impact on members	If the decision to remove of a drug will impact patients negatively because there are no comparable therapeutic alternatives left in the formulary to treat the disease or condition.	Advance Control Formulary and Standard Opt Out Formulary. Formulary, or drug list drugs used for the disease or condition in question.	Drug-dependent qualitative measure: Large impact occurs when the formulary in question does not have enough drugs choices to treat the disease or condition. Low impact occurs when the formulary in question has multiple drugs

			choices to treat the disease or condition.

Specialty Drug designation:

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

Factors	Definitions	Sources	Standards
Risk profile	The risk characteristics associated with the drug such as box warnings, REMS, adverse drug reactions and patient monitoring requirements.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA.	As assigned by the FDA. For further information, please see: 1. FDA's Application of Statutory Factors in Determining When a REMS is Necessary: Guidance for Industry. 2. Black box" 101: How the Food and Drug Administration evaluates, communicates, and manages drug benefit/risk https://www.jacionline.org/article/S0091-6749(05)02325-0/fulltext

		https://www.micromedexsolutions.com	
Safety and effectiveness	The level of patient proficiency needed for self-management and maintaining adherence, as well as any required therapeutic response monitoring and dose adjustments.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www.micromedexsolutions.com	As assigned by the FDA and described in the FDA labeling. For further information, please see: FDA's Labeling Resources for Human Prescription Drugs. https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs
Indication for use and cost	The indication is what the drug is used for.	Drug labeling approved by the U.S. Food and Drug Administration (FDA)	There is no set threshold, since this is a qualitative comparison.

	The cost is a relative price measured in comparison to other drugs for the same indication. The complexity of the condition where the drug is intended for use (e.g., rare, chronic) and its actual or anticipated cost.	US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Cost information internal database.	The indication is as assigned in the drug labeling by the FDA. The cost is a relative measure looking at price of a drug measured in comparison to the price of another drug or group of drugs that are used for the same indication. A cost can be higher than, similar to, or lower than other drugs that are used for the same indication.
Route of administration or delivery systems	The level of complexity to administer the drug, such as via infusion, injection or inhalation and whether the administration of the drug requires ancillary supplies and/or a device.	Drug labeling approved by the U.S. Food and Drug Administration (FDA) US Food and Drug Administration Labeling is accessible via National Library of Medicine. The DailyMed database. https://dailymed.nlm.nih.gov/dailymed/index.cfm Centers for Medicare & Medicaid Services accepted drug compendia Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc. https://online.lexi.com/lco/action/login Micromedex (electronic version). IBM Watson Health, Greenwood Village,	A route is required by the FDA labeling. Standard routes of administration are known by clinicians making decisions to be easier or more difficult to execute by a patient or may require administration by a health care provider.

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

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

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

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

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

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

The meeting minutes reveal that no separate meetings occur to vote on decision about MH/SUD drugs vs. M/S drugs. Examination of the past two years FRC Meeting minutes revealed that no different committee members were used in decisions for MH/SUD drugs from M/S drugs, and factors used brand/generic status, pipeline new to market information, line of business (commercial, Medicare part D, etc.), information found in FDA approved drug labeling (drug class, category, brand name, dosage form, etc.) are explicit in the minutes, and are not different for MH/SUD drugs than for M/S drugs. The factors availability of therapeutic alternatives and cost effectiveness and potential impact on members, are not explicit in

the FRC minutes. Nevertheless, decisions about MH/SUD drugs do not have a different process from M/S drugs or reached more restrictive decisions. For example, on minutes dated 01/06/2022 an FRC decision was made to bring forth a business formulary recommendation to P&T Committee about adding new SUD naloxone spray generic launch to tier 1 for ACF and SOO formularies, the same decision was made for the M/S drug adapalene-benzoyl peroxide gel due to a generic launch. Additionally, on minutes dated 04/06/2022 an FRC decision was made to bring forth a business formulary recommendation to P&T Committee about adding new MH drug LOREEV XR cap to tier 3, and the same decision was made for new M/S drug orphenadrine, aspirin, and caffeine combination tab to tier 3.

Factors	**SUD Drug** **Sources for** naloxone spray generic launch add to Tier 1	**M/S Drug** **Sources for** adapalene-benzoyl peroxide gel launch **add to Tier 1**
Brand or generic status of the drug	DailyMed - NALOXONE HYDROCHLORIDE- naloxone hydrochloride nasal spray inhalant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=68723486-8f21-4299-b380-7d5e3f9657b6	DailyMed - ADAPALENE AND BENZOYL PEROXIDE gel (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=05babd5f-18ab-4646-8962-cb000ed0f9a8
Impact of generic drugs or drugs designated to become available over-the-counter	DailyMed - NALOXONE HYDROCHLORIDE- naloxone hydrochloride nasal spray inhalant (nih.gov)https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=68723486-8f21-4299-b380-7d5e3f9657b6 1. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm Note this drug was not OTC in 2021.	DailyMed - ADAPALENE AND BENZOYL PEROXIDE gel (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=05babd5f-18ab-4646-8962-cb000ed0f9a8 1. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm Note this drug was not OTC in 2021.
Brand and generic pipeline	Pipeline website generic launch announced: https://www.us.sandoz.com/news/media-releases/sandoz-launches-authorized-generic-narcan-naloxone-hydrochloride-nasal-spray-4	Pipeline website generic launch announced: https://www.businesswire.com/news/home/20211201005573/en/
Line of business	Commercial	Commercial
Availability of therapeutic alternatives	Available therapeutic drugs information is found at: Substance Abuse and Mental Health Services Administration – SAMHSA – Opioid Overdose	Available therapeutic drugs information is found at: Journal of the American Academy of Dermatology - Guidelines of care for the management of acne vulgaris

	https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/opioid-overdose	https://www.jaad.org/article/S0190-9622(15)02614-6/fulltext
Indication for use and cost (cost-effectiveness)	Generic relative cost is lower than brand	Generic relative cost is lower than brand
Potential impact on members	This is a new drug. The decision was to add to formulary preferred, the impact is not negative since this offers another therapeutic option to many existing ones.	This is a new drug. The decision was to add to formulary as preferred, the impact is not negative since this offers another therapeutic option to many existing ones.

The meeting minutes reveal that no separate meetings occur to vote on decision about MH/SUD drugs vs. M/S drugs. Examination of the past two years P&T Committee minutes revealed no different committee members were used in decisions for MH/SUD drugs from M/S drugs, and factors used brand/generic status, pipeline new to market information, line of business (commercial, Medicare part D, etc.), information found in FDA approved drug labeling (drug class, category, brand name, dosage form, etc.) are explicit in the minutes, and are not different for MH/SUD drugs than for M/S drugs. For example, in P&T Committee minutes dated 6/2/2021 a decision was made to add MH drug Qelbree (viloxazine ER) oral capsules to the formularies with a non-preferred status. There was a note about the rationale for a decision about this drug stating the generic atomoxetine and/or guanfacine ER. On the same minutes, a decision was made to add the M/S drug Zegalogue (dasiglucagon) SC injection at the non-preferred Brand Specialty tier. The minutes indicate that the same clinical pharmacist with a Pharm D provided an overview of the drugs to the committee including FDA Approved indications, efficacy and safety information, clinical trials and clinical rationale in supporting materials. Comments about the MH drug was made by an MD Psychiatry Specialist and a MD Pediatrics Specialist; a comparable MD -PhD in Endocrinology Specialist provided comments about the M/S drug. The factors considered were that both these drugs are brand and do not have a generic or OTC version available, there is no pipeline information available from the manufacturers, the line of business is the same (commercial) for both drugs, clinical comments from the comparable credentialled physicians considered alternative therapies in the a comparable manner, and not comment was more stringent because a drug was used for mental health, cost related factors were not considered by P&T Committee and the impact on members was similar, since the decision was the same, to add to a non-preferred tier.

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

Factors	**Sources for Qelbree (viloxazine ER) Mental Health Drug**	**Sources for Zegalogue (dasiglucagon) SC injection Medical/Surgical Drug**
Brand or generic status of the drug	DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a	DailyMed - ZEGALOGUE- dasiglucagon injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=14704879-872c-4967-8779-04a3bbdfb4e6
Impact of generic drugs or drugs designated to become available over-the-counter	2. DailyMed - QELBREE- viloxazine hydrochloride capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aedf408d-0f84-418d-9416-7c39ddb0d29a 3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm	2. DailyMed - ZEGALOGUE- dasiglucagon injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=14704879-872c-4967-8779-04a3bbdfb4e6 3. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm
Brand and generic pipeline	Pipeline website: https://www.supernus.com/research-development	Pipeline website: https://www.novonordisk.com/science-and-technology/r-d-pipeline.html
Line of business	Commercial	Commercial
Availability of therapeutic alternatives	The comment in minutes considered the availability of other brand and generics and advantages of other formulary to add the comment about agents in comparison, and that this drug would generally be a third-line or fourth line use given the availability of numerous alternatives.	The comment in minutes considered the availability of other brand and generics stating that this drug is a positive ready-to-use product rather than products that must be reconstituted, and having the benefit of long shelf live, and patients needed less frequent refills advantages.
Indication for use and cost (cost-effectiveness)	This factor is not considered by the P&T Committee.	This factor is not considered by the P&T Committee.

Potential impact on members	This is a new drug. The decision was to add to formulary as non-preferred, the impact is not negative since this offers another therapeutic option to many existing ones.	This is a new drug. The decision was to add to formulary as non-preferred, the impact is not negative since this offers another therapeutic option to many existing ones.

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

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

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

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

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

distribution deemed as limited; dispensing requirements needing coordination of care; indication for use as non-infectious uveitis affecting the posterior segment of the eye and for diabetic macular edema.

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

Factors	**Sources for Zyprexa Relprevv**	**Sources for Ozurdex**
Risk profile	1. DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241 2. Zyprexa Relprevv (fda.gov) https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems	1. DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f 2. No REMS found searching the Approved Risk Evaluation and Mitigation Strategies (REMS) (fda.gov) https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
Safety and effectiveness	Zyprexa Relprevv - olanzapine pamoate kit medication guide https://pi.lilly.com/us/zyprexa_relprevv_medguide.pdf	See patient education found at OZURDEX® Resources for Your Practice | OZURDEX® for HCPs https://hcp.ozurdex.com/resources
Indication for use and cost	1. DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241 2. Cost is found in internal database to be greater than olanzapine generic tablets and to other drugs for schizophrenia.	1. DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f 2. Cost is found in internal database to be greater than dexamethasone generic ophthalmic and to other drugs for ocular inflammation.
Route of administration or delivery systems	DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241	DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f

Dispensing requirements	DailyMed - ZYPREXA RELPREVV- olanzapine pamoate kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f9a73185-88de-4d7b-b3c0-bbf231483241	DailyMed - OZURDEX- dexamethasone implant (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b204f44-6e8a-4d17-803c-268f0b04679f

Methodology used for in operations analysis Formulary Tiering and Design:

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

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

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

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

Methodology used for in operations analysis Specialty Drug designation:

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

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

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

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

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

Methodology data for 2021 requests matched by drug GPI to the drug list was reviewed. Quality control of the data by a PBM pharmacist found that 15% of the prior authorizations processed did not match GPI. These non-matching GPIs were also reviewed and are here reported, since they did not match due to the drug not being present in the drug list.

There are no SUD drugs being denied.

Only one drug in MH was found to be denied for non-covered: **Viibryd (vilazodone)**

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

FORMULARY TIERING ANALYSIS								
Plan: State of MD - AETNA - Advanced Control Formulary - 2021								
Category		Analysis						
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	966	206	794	219	188	2,373	**58.6%**
	% of Drug Count per Tier	40.7%	8.7%	33.5%	9.2%	7.9%		
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	119	10	38	0	6	173	**74.6%**
	% of Drug Count per Tier	68.8%	5.8%	22.0%	0.0%	3.5%		
Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	9	1	7	1	1	19	**57.9%**
	% of Drug Count per Tier	47.4%	5.3%	36.8%	5.3%	5.3%		

* 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

SPECIALTY DRUG CLASSIFICATION ANALYSIS								
Plan: State of MD - AETNA - Advanced Control Formulary - 2021								
Category		Analysis						
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	54	26	37	213	179	509	21.5%
	% of Specialty Drugs per Tier	10.6%	5.1%	7.3%	41.8%	35.2%		
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	0	0	0	0	6	6	3.5%
	% of Specialty Drugs per Tier	0.0%	0.0%	0.0%	0.0%	100.0%		
Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	0	0	0	1	1	2	10.5%
	% of Specialty Drugs per Tier	0.0%	0.0%	0.0%	50.0%	50.0%		

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

Comparative Analysis for Specialty drug designation 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 Hetlioz 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

FORMULARY TIERING ANALYSIS								
Plan: State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021								
Category		Analysis						
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	1,162	269	636	212	188	2,467	66.6%
	% of Drug Count per Tier	47.1%	10.9%	25.8%	8.6%	7.6%		
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	135	17	36	0	6	194	78.4%
	% of Drug Count per Tier	69.6%	8.8%	18.6%	0.0%	3.1%		
Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred**
	Drug Count by Tier	10	1	5	1	1	18	66.7%
	% of Drug Count per Tier	55.6%	5.6%	27.8%	5.6%	5.6%		

* 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 generics and Tier 2 preferred brands

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.
- 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

SPECIALTY DRUG CLASSIFICATION ANALYSIS								
Plan: State of MD - AETNA - Standard Opt-Out Formulary with ACSF - 2021								
Category		Analysis						
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	54	26	13	206	179	478	19.4%
	% of Specialty Drugs per Tier	11.3%	5.4%	2.7%	43.1%	37.4%		
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	0	0	0	0	6	6	3.1%
	% of Specialty Drugs per Tier	0.0%	0.0%	0.0%	0.0%	100.0%		
Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Specialty Drugs	% Specialty
	Specialty Drug Count by Tier	0	0	0	1	1	2	11.1%
	% of Specialty Drugs per Tier	0.0%	0.0%	0.0%	50.0%	50.0%		

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

Comparative Analysis for Specialty drug designation 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.

Tiering Designation

The MIA Instructions for Step 5 do not describe an exact required methodology that needs to be used for counting drugs for a formulary analysis. Assuming that MIA is referring to the Specialty Drug Classification Analysis Table as "the Specialty tables" and to Formulary Tiering Analysis Table as the "non-Specialty tables" are not comparable because Specialty Drug Classification Designation is different from Formulary Tiering. There are drugs that are not designated specialty that are in specialty Tier 4 and 5 and counted in the Formulary Tiering Analysis Table, explaining the higher numbers found in such table. The fact that there are lower amount Specialty M/S than the total, is because there is 54 Tier 1, 26 Tier 2 and 37 Tier 3 M/S drugs designated as specialty in other tiers, and that are also added to Tier 4 and Tier 5 to get to the total, which is 54+26+37+213+179 = 509. The fact that the totals in the SUD and MH tables "correlate" is because there are no MH/SUD drugs with specialty designation placed in non-specialty tiers 1, 2, and 3, that is there are zero Tier 1, zero Tier 2, and zero Tier 3 specialty designated drugs for MH and SUD, that is 0+0+0+0+6 = 6 for MH and 0+0+0+1+1=2 for SUD. Both tables demonstrate that the formulary <u>overall</u> is not placing MH/SUD drugs in greater more restricting numbers in higher non-preferred tiers or designating drugs as specialty in greater more restricting numbers than for M/H drugs.

The MIA Instructions for Step 5 do not describe an exact required methodology that needs to be used for counting drugs for a formulary analysis. Assuming that MIA is referring to the Specialty Drug Classification Analysis Table as "the Specialty tables" and to Formulary Tiering Analysis Table as the "non-Specialty tables" are not comparable because Specialty Drug Classification Designation is different from Formulary Tiering. There are drugs that are not designated specialty that are in specialty Tier 4 and 5 and counted in the Formulary Tiering Analysis Table, explaining the higher numbers found in such table. The fact that there are lower amount Specialty M/S than the total, is because there is 54 Tier 1, 26 Tier 2 and 13 Tier 3 M/S drugs designated as specialty in other tiers, and that are also added to Tier 4 and Tier 5 to get to the total, which is 54+26+13+206+179 = 478. The fact that the totals in the SUD and MH tables "correlate" is because there are zero Tier 1, zero Tier 2, and zero Tier 3 drugs for MH and SUD, that is 0+0+0+0+6 = 6 for MH and 0+0+0+1+1=2 for SUD, that is no MH/SUD drugs with specialty designation placed in non-specialty tiers 1, 2, and 3. Both tables demonstrate that the formulary overall is not placing MH/SUD drugs in greater more restricting numbers in higher non-preferred tiers or designating drugs as specialty in greater more restricting numbers than for M/H drugs.]

AETNA response Advanced Control Formulary – 2021 Tiering – preferred tiers are tier 1, 2 and 4 (generic, branded and specialty respectively)	**MIA analysis of data not discussed/explained by AETNA where the data appears to indicate more stringency in covering branded M/H and SUD medications with greater focus on use of generics for MH and SUD conditions**	Response
• *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*	1. Tier 2: Only 5.3% of SUD and 5.8% of MH medications versus 8.7% of M/S medications while Tier 1: 47.4% SUD and 68.8% of MH medications versus 40.7% of M/S medications. 2. Tier 4: Of the medications considered Specialty (in Tiers 4 and 5), none of the 6 MH medications was preferred	1. The MIA Instructions for Step 5 do not describe an exact required methodology that needs to be used for counting drugs for a formulary analysis. Our methodology looked at the <u>overall</u> drugs placed on more accessible preferred positions and did not find a more stringent overall treatment for MH and SUD. Tier 1 is the lowest copay tier providing the most access to members. 68.8 % of MH drugs and 47.4 % of SUD drugs are on Tier 1 which is more than the 40.7% for M/S drugs. Tier 2 has one SUD drug Zubsolv[1], and 10 MH drugs: Trintellix[2], Perseris[3], Abilify Maintena Vial[4], Abilify Maintena Pre-Filled Syringe [4], Vraylar Caps[5], Vraylar Pack[5], Latuda[6], Vyvanse Caps[7], Vyvanse Chewable[7], Mydayis Caps[8]; and 206 M/S drugs, for example Biktarvy[9], Soliqua[10] and Ubrelvy[11]. PBM Clinicians further analyzed the factors used to place these 11 drugs in Tier 2. Findings: all 10 MH plus one SUD drugs and the 3 M/S example drugs are brands[1-11] , none where designated to become available over-the-counter[12], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[13], the line of business (commercial) did not require that these drugs be placed in a particular tier[14], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in tier 1 or at higher tiers[1-11], therapeutic alternative drugs were plentiful and available in tier 1 already[15]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in tier 1 or other tiers as this was not indicated in the minutes[16]. We looked at the following sources to inform each factor: 1. DailyMed - ZUBSOLV- buprenorphine hydrochloride and naloxone hydrochloride tablet, orally disintegrating (nih.gov)

57.9% of the drugs at a preferred formulary tier.	compared to 53.8% of the 407 M/S medications considered Specialty	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5f5cfcfe-d52b-49e6-8fe4-550477332dd2 2. DailyMed - TRINTELLIX- vortioxetine tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1a5b68e2-14d0-419d-9ec6-1ca97145e838 3. DailyMed - PERSERIS- risperidone kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a4f21b1a-5691-4b14-a56d-651962d06f39 4. DailyMed - ABILIFY MAINTENA- aripiprazole kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ee49f3b1-1650-47ff-9fb1-ea53fe0b92b6 5. DailyMed - VRAYLAR- cariprazine capsule, gelatin coated VRAYLAR- cariprazine kit (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4b5f7c65-aa2d-452a-b3db-bc85c06ff12f 6. DailyMed - LATUDA- lurasidone hydrochloride tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=afad3051-9df2-4c54-9684-e8262a133af8 7. DailyMed - VYVANSE- lisdexamfetamine dimesylate capsule VYVANSE- lisdexamfetamine dimesylate tablet, chewable (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=704e4378-ca83-445c-8b45-3cfa51c1ecad 8. DailyMed - MYDAYIS- dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate capsule, extended release (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=141a7970-3f06-44ea-9ab7-aeece2c085fc 9. DailyMed - BIKTARVY- bictegravir sodium, emtricitabine, and tenofovir alafenamide fumarate tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=664cb8f0-1f65-441b-b0d9-ba3d798be309 10. DailyMed - SOLIQUA 100/33- insulin glargine and lixisenatide injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4bba538b-cf7c-4310-ae8f-cb711ed21bcc 11. DailyMed - UBRELVY- ubrogepant tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fd9f9458-fd96-4688-be3f-f77b3d1af6ab 12. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm

		13. CVS Health Payor Solutions. Drugs to Watch. Drug Pipeline https://payorsolutions.cvshealth.com/tags/drug-pipeline 14. Per regulatory requirements federal or state as applicable. 15. Advanced Control Formulary – 2021 Tier 1 consistent with Clinical guidelines and standards of care for each disease accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example, https://www.guidelinecentral.com/guidelines/ 16. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file 2. The 6 MH drugs placed in the non-preferred Tier 5 are the antidepressants Spravato 56 mg and 86 mg, the antipsychotics Nuplazid tablets and capsules, and Hetlioz capsule and the hypnotics Hetlioz LQ suspension. PBM Clinicians further analyzed the factors used to place these 6 drugs in the non-preferred tier. Findings: all 6 drugs are brands[1,2,3], none where designated to become available over-the-counter[4], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[5], the line of business (commercial) did not require that these drugs be placed in a particular tier[6], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3], therapeutic alternative drugs were plentiful and available in lower tiers already[7]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[8]. We looked at the following sources to inform each factor: 1. DailyMed - SPRAVATO- esketamine hydrochloride solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d81a6a79-a74a-44b7-822c-0dfa3036eaed 2. DailyMed - NUPLAZID- pimavanserin tartrate capsule NUPLAZID- pimavanserin tartrate tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e6bea44-57d6-4bac-9328-46e1ee59f83b 3. DailyMed - HETLIOZ- tasimelteon capsule HETLIOZ LQ- tasimelteon suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90 4. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm 5. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com)cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 6. Per regulatory requirement (State or Federal as applicable)

		7. Advanced Control Formulary – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives available, and indicated by these sources to be for such treatment: a. American Psychological Association (APA) Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts. https://www.apa.org/depression-guideline b. American Psychological Association (APA) Treatment of Patients with Schizophrenia. https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841 c. American Academy of Sleep Medicine – Pharmacologic Treatment of Chronic Insomnia in Adults. https://jcsm.aasm.org/doi/10.5664/jcsm.6470 8. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file PBM Clinicians further analyzed the factors used to place four example drugs of the 407 M/S medications in Tier 4, to ascertain that the 6 MH drugs placed in the non-preferred Tier 5 are not being placed more stringently. Examples of M/S drugs are: Ibrance[1], Kisqali[2], Kesimpta[3] and Sprycel[4]. Findings: all 4 drugs are brands[1-4], none where designated to become available over-the-counter[5], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[6], the line of business (commercial) did not require that these drugs be placed in a particular tier[7], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3,4], therapeutic alternative drugs were NOT plentiful and available in lower tiers warranting that they NOT be placed int the highest formulary tier available[8]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[9]. We looked at the following sources to inform each factor: 1. DailyMed - Search Results for ibrance (nih.gov) https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=ibrance&pagesize=200&page=1 2. DailyMed - KISQALI- ribociclib tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aaeaef94-f3f5-4367-8ea2-b181d7be2da8 3. DailyMed - KESIMPTA- ofatumumab injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6a8a3f53-2062-48ff-9dbe-b939df133ca3 4. DailyMed - SPRYCEL- dasatinib tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4764f37b-c9e6-4ede-bcc2-8a03b7c521df 5. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm

		6. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 7. Per regulatory requirement (State or Federal as applicable) 8. Advanced Control Formulary – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives consistent with guideline examples found: Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example: a. https://www.guidelinecentral.com/guidelines/ b. National Comprehensive Cancer Network https://www.nccn.org/guidelines/category_1 9. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file
Standard Opt-Out Formulary – 2021	**MIA Analysis**	
• *The Medical/Surgical category has 19.4% of the drugs with a Specialty drug Designation.* • *The Mental Health category has 3.1% of the drugs with a Specialty drug Designation.* • *The Substance Use Disorder category has 11.1% of the*	Tier 4: 0% of the 6 Specialty MH medications are preferred while 53.5% (206/385) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)	The 6 MH drugs placed in the non-preferred Tier 5 are the antidepressants Spravato 56 mg and 86 mg, the antipsychotics Nuplazid tablets and capsules, and Hetlioz capsule and the hypnotics Hetlioz LQ suspension. PBM Clinicians further analyzed the factors used to place these 6 drugs in the non-preferred tier. Findings: all 6 drugs are brands[1,2,3], none where designated to become available over-the-counter[4], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[5], the line of business (commercial) did not require that these drugs be placed in a particular tier[6], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3], therapeutic alternative drugs were plentiful and available in lower tiers already[7]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[8]. We looked at the following sources to inform each factor: 1. DailyMed - SPRAVATO- esketamine hydrochloride solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d81a6a79-a74a-44b7-822c-0dfa3036eaed 2. DailyMed - NUPLAZID- pimavanserin tartrate capsule NUPLAZID- pimavanserin tartrate tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e6bea44-57d6-4bac-9328-46e1ee59f83b 3. DailyMed - HETLIOZ- tasimelteon capsule HETLIOZ LQ- tasimelteon suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90

drugs with a Specialty drug Designation.		4. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm 5. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 6. Per regulatory requirement state or federal as applicable 7. Standard Opt Out – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives and indicated by these sources to be for such treatment: a. American Psychological Association (APA) Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts. https://www.apa.org/depression-guideline b. American Psychological Association (APA) Treatment of Patients with Schizophrenia. https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841 c. American Academy of Sleep Medicine – Pharmacologic Treatment of Chronic Insomnia in Adults. https://jcsm.aasm.org/doi/10.5664/jcsm.6470 8. utilization trends, plan sponsor cost, applicable manufacturer agreements on file PBM Clinicians further analyzed the factors used to place some example drugs of the 206 M/S medications in Tier 4, to ascertain that the 6 MH drugs placed in the non-preferred Tier 5 are not being placed more stringently. Examples are: Ibrance[1], Kisqali[2], Kesimpta[3] and Sprycel[4]. Findings: all 4 drugs are brands[1,2,3,4], none where designated to become available over-the-counter[5], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[6], the line of business (commercial) did not require that these drugs be placed in a particular tier[7], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3,4], therapeutic alternative drugs were NOT plentiful and available in lower tiers warranting that they NOT be placed int the highest formulary tier available[8]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[9]. We looked at the following sources to inform each factor: 1. DailyMed - Search Results for ibrance (nih.gov) https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=ibrance&pagesize=200&page=1 2. DailyMed - KISQALI- ribociclib tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aaeaef94-f3f5-4367-8ea2-b181d7be2da8 3. DailyMed - KESIMPTA- ofatumumab injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6a8a3f53-2062-48ff-9dbe-b939df133ca3

		4. DailyMed - SPRYCEL- dasatinib tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4764f37b-c9e6-4ede-bcc2-8a03b7c521df 5. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm 6. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 7. Per regulatory requirement state or federal as applicable 8. Standard Opt Out– 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives consistent with guideline examples found: a. Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example: b. https://www.guidelinecentral.com/guidelines/ c. National Comprehensive Cancer Network https://www.nccn.org/guidelines/category_1 9. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file

AETNA Response in Step 5 Advanced Control Formulary - 2021	**MIA analysis of data not discussed/ explained by AETNA where the data appear to indicate that more stringency in covering MH medications at preferred tier**	Responses
• The Medical/Surgical category has 21.5% of the	1.Tier 4: 0% of the 6 Specialty MH medications are preferred	The 6 MH drugs placed in the non-preferred Tier 5 are the antidepressants Spravato 56 mg and 86 mg, the antipsychotics Nuplazid tablets and capsules, and Hetlioz capsule and the hypnotics Hetlioz LQ suspension. PBM clinicians further analyzed the factors used to place these 6 drugs in the non-preferred tier. Findings: all 6 drugs are brands[1,2,3], none where designated to become available over-the-counter[4],

drugs with a Specialty drug Designation. • The Mental Health category has 3.5% of the drugs with a Specialty drug Designation. • The Substance Use Disorder category has 10.5% of the drugs with a Specialty drug Designation**.**	while 54.3% (213/392) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)	relevant pipeline brand or generic drugs in 2021 showed no alternatives available[5], the line of business (commercial) did not require that these drugs be placed in a particular tier[6], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3], therapeutic alternative drugs were plentiful and available in lower tiers already[7]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[8]. We looked at the following sources to inform each factor: 1. DailyMed - SPRAVATO- esketamine hydrochloride solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d81a6a79-a74a-44b7-822c-0dfa3036eaed 2. DailyMed - NUPLAZID- pimavanserin tartrate capsule NUPLAZID- pimavanserin tartrate tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e6bea44-57d6-4bac-9328-46e1ee59f83b 3. DailyMed - HETLIOZ- tasimelteon capsule HETLIOZ LQ- tasimelteon suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90 4. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm 5. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 6. Per regulatory requirement state or federal as applicable 7. Advanced Control Formulary – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives consistent with clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. a. American Psychological Association (APA) Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts. https://www.apa.org/depression-guideline b. American Psychological Association (APA) Treatment of Patients with Schizophrenia. https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841 c. American Academy of Sleep Medicine – Pharmacologic Treatment of Chronic Insomnia in Adults. https://jcsm.aasm.org/doi/10.5664/jcsm.6470 8. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file

		PBM clinicians further analyzed the factors used to place some example drugs of the 213 M/S medications in Tier 4, to ascertain that the 6 MH drugs placed in the non-preferred Tier 5 are not being placed more stringently. Examples are: Ibrance[1], Kisqali[2], Kesimpta[3] and Sprycel[4]. Findings: all 4 drugs are brands[1,2,3,4], none where designated to become available over-the-counter[5], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[6], the line of business (commercial) did not require that these drugs be placed in a particular tier[7], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1-,4], therapeutic alternative drugs were NOT plentiful and available in lower tiers warranting that they NOT be placed int the highest formulary tier available[8]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[9]. We looked at the following sources to inform each factor: 1. DailyMed - Search Results for ibrance (nih.gov) https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=ibrance&pagesize=200&page=1 2. DailyMed - KISQALI- ribociclib tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aaeaef94-f3f5-4367-8ea2-b181d7be2da8 3. DailyMed - KESIMPTA- ofatumumab injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6a8a3f53-2062-48ff-9dbe-b939df133ca3 4. DailyMed - SPRYCEL- dasatinib tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4764f37b-c9e6-4ede-bcc2-8a03b7c521df 5. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm 6. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 7. Per regulatory requirements state or federal as applicable. 8. Advanced Control Formulary – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives consistent with guideline examples found: Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example: a. https://www.guidelinecentral.com/guidelines/ b. National Comprehensive Cancer Network https://www.nccn.org/guidelines/category_1

		9. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file
Standard Opt-Out Formulary – 2021	**MIA Analysis**	
• The Medical/Surgical category has 19.4% of the drugs with a Specialty drug Designation. • The Mental Health category has 3.1% of the drugs with a Specialty drug Designation. • The Substance Use Disorder category has 11.1% of the drugs with a Specialty drug Designation.	Tier 4: 0% of the 6 Specialty MH medications are preferred while 53.5% (206/385) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)	The 6 MH drugs placed in the non-preferred Tier 5 are the antidepressants Spravato 56 mg and 86 mg, the antipsychotics Nuplazid tablets and capsules, and Hetlioz capsule and the hypnotics Hetlioz LQ suspension. PBM clinicians further analyzed the factors used to place these 6 drugs in the non-preferred tier. Findings: all 6 drugs are brands[1,2,3], none where designated to become available over-the-counter[4], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[5], the line of business (commercial) did not require that these drugs be placed in a particular tier[6], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3], therapeutic alternative drugs were plentiful and available in lower tiers already[7]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[8]. We looked at the following sources to inform each factor: 1. DailyMed - SPRAVATO- esketamine hydrochloride solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d81a6a79-a74a-44b7-822c-0dfa3036eaed 2. DailyMed - NUPLAZID- pimavanserin tartrate capsule NUPLAZID- pimavanserin tartrate tablet, coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1e6bea44-57d6-4bac-9328-46e1ee59f83b 3. DailyMed - HETLIOZ- tasimelteon capsule HETLIOZ LQ- tasimelteon suspension (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca4a9b63-708e-49e9-8f9b-010625443b90 4. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm 5. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 6. Per regulatory requirement state or federal as applicable 7. Standard Opt Out – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives consistent with clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors.

		a. American Psychological Association (APA) Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts. https://www.apa.org/depression-guideline b. American Psychological Association (APA) Treatment of Patients with Schizophrenia. https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841 c. American Academy of Sleep Medicine – Pharmacologic Treatment of Chronic Insomnia in Adults. https://jcsm.aasm.org/doi/10.5664/jcsm.6470 8. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file PBM clinicians further analyzed the factors used to place some example drugs of the 206 M/S medications in Tier 4, to ascertain that the 6 MH drugs placed in the non-preferred Tier 5 are not being placed more stringently. Examples are: Ibrance[1], Kisqali[2], Kesimpta[3] and Sprycel[4]. Findings: all 4 drugs are brands[1,2,3,4], none where designated to become available over-the-counter[5], relevant pipeline brand or generic drugs in 2021 showed no alternatives available[6], the line of business (commercial) did not require that these drugs be placed in a particular tier[7], the FDA drug labeling information did not indicate unique drug information warranting that these drugs should be widely available in lower tiers[1,2,3,4], therapeutic alternative drugs were NOT plentiful and available in lower tiers warranting that they NOT be placed int the highest formulary tier available[8]; utilization trends, plan sponsor cost, applicable manufacturer agreements and potential impact on members did not indicate that these should be placed in lower tiers[9]. We looked at the following sources to inform each factor: 1. DailyMed - Search Results for ibrance (nih.gov) https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=ibrance&pagesize=200&page=1 2. DailyMed - KISQALI- ribociclib tablet, film coated (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aaeaef94-f3f5-4367-8ea2-b181d7be2da8 3. DailyMed - KESIMPTA- ofatumumab injection, solution (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6a8a3f53-2062-48ff-9dbe-b939df133ca3 4. DailyMed - SPRYCEL- dasatinib tablet (nih.gov) https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4764f37b-c9e6-4ede-bcc2-8a03b7c521df 5. OTC - Over The Counter (fda.gov) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfivd/search.cfm

		6. cvs-health-payor-solutions-specialty-pipeline-drugs-to-watch-q1-to-q2-2021.pdf (cvshealth.com) 7. Per regulatory requirement state or federal as applicable 8. Standard Opt Out Formulary – 2021 Tier 1 antidepressants, antipsychotics and hypnotic alternatives consistent with guideline examples found: Clinical guidelines and standards of care for each disease are accessible via web search or via databases that enable users to execute searches across multiple clinical authors. For example: a. https://www.guidelinecentral.com/guidelines/ b. National Comprehensive Cancer Network https://www.nccn.org/guidelines/category_1 9. utilization trends, plan sponsor cost, applicable manufacturer agreements are on file

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

Advanced Control Formulary 2021 Plan – Aetna preferred tier

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

Standard Opt-Out Formulary 2021 Plan – Aetna preferred tier

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

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

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

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

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

Findings and Conclusion for Specialty Designation: The basis for the conclusion that both as written and in operation, the processes, evidentiary standards, and factors used to impose the Specialty Drug Designation NQTL on MH/SUD drugs are comparable to and applied no more stringently than the processes, strategies, evidentiary standards, and factors used to impose the NQTL on M/S drugs is the analysis findings as follows. The written materials and minutes analysis revealed that as written factors and standards used for drugs designated as a Specialty drug are the same and are not used differently or more restrictively based on a drug being for M/S or MH/SUD treatment. The review and comparison

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

Advanced Control Formulary 2021 Plan - Aetna Specialty drug designation

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

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

- The Medical/Surgical category has 19.4%
- The Mental Health category has 3.1%
- The Substance Use Disorder category has 11.1%

- ACF Tier 4: 0% of the 6 Specialty MH medications are preferred while 54.3% (213/392) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)
- SOO Tier 4: 0% of the 6 Specialty MH medications are preferred while 53.5% (206/385) of M/S Specialty Medications in Tiers 4 and 5 are preferred (in Tier 4)

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

pharmacy. This analysis was done by PBM Clinicians, they are pharmacists, and they made no recommendations regarding NQTLs applied to MH/SUD and M/S drugs. No variation in the use of PBM Clinicians for MH/SUD compared to M/S NQTL analyses.

8. <u>Case Management</u>

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

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

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

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

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

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

9. Process for Assessment of New Technologies

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

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

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

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

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

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

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

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

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

certification, and hospital privileges requirements. The Credentialing & Performance Committee, which is comprised of participating providers in various specialties including behavioral health, is authorized to make final determinations with respect to exceptions to unencumbered license and professional competence and conduct requirements. Detailed participation criteria are posted here: https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/2023-network-participation-criteria-document.pdf **Plan language:** HI MD HCOC00110 05, page 3-8 ## Who provides the care ### Network providers We have contracted with **providers** in the service area to provide **covered services** to you. These **providers** make up the network for your plan. To get network benefits, you must use **network providers**. There are some exceptions: • **Emergency services** – see the description of **emergency services** in the *Coverage and exclusions* section. • Urgent care – see the description of urgent care in the *Coverage and exclusions* section. • Clinical trials – see the description of clinical trials in the *Coverage and exclusions* section. • **Network provider** not available without unreasonable delay/travel or does not have the training and expertise to treat your condition – You can get services from an **out-of-network provider**. You must request approval from us before you get the care. Contact us for assistance.	providers in various specialties including behavioral health, is authorized to make final determinations with respect to exceptions to unencumbered license and professional competence and conduct requirements. Detailed participation criteria are posted here: https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/healthcare-professionals/documents-forms/2023-network-participation-criteria-document.pdf **HI MD HCOC00170 05 page 2-8** **Behavioral health provider** A **health professional** who is properly licensed or certified to provide covered services for mental health and **substance related disorders** in the state where the person practices. **Health professional** A person who is authorized by law to provide health care services to the public; for example, **physicians**, nurses and physical therapists. **Hospital** An institution licensed as a **hospital** by applicable law, and accredited by The Joint Commission (TJC). This is a place that offers medical care. Patients can stay overnight for care. Or they can be treated and leave the same day. All **hospitals** must meet set standards of care. They can offer general or acute care. They can also offer service in one area, like rehabilitation. **Physician** A **health professional** trained and licensed to practice and prescribe medicine under the laws of the state where they practice; specifically,

- Use of a **provider** not in the network under continuity of care – see the description of continuity of care in the *Keeping a provider you go to now (continuity of care)* section below.
- Transplants – see the description of transplant services in the *Coverage and exclusions* section.

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Health professional

A person who is authorized by law to provide health care services to the public; for example, **physicians**, nurses and physical therapists.

Hospital

An institution licensed as a **hospital** by applicable law, and accredited by The Joint Commission (TJC). This is a place that offers medical care. Patients can stay overnight for care. Or they can be treated and leave the same day. All **hospitals** must meet set standards of care. They can offer general or acute care. They can also offer service in one area, like rehabilitation.

Physician

A **health professional** trained and licensed to practice and prescribe medicine under the laws of the state where they practice; specifically, doctors of medicine or osteopathy. Under some plans, a **physician** can also be a **primary care physician** (**PCP**).

Skilled nursing facility

A facility specifically licensed as a **skilled nursing facility** by applicable laws to provide skilled nursing care. **Skilled nursing facilities** also include:

- Rehabilitation **hospitals**
- Portions of a rehabilitation **hospital**
- A **hospital** designated for skilled or rehabilitation services

doctors of medicine or osteopathy. Under some plans, a **physician** can also be a **primary care physician** (**PCP**).

Psychiatric hospital

An institution licensed or certified as a **psychiatric hospital** by applicable laws to provide a program for the diagnosis, evaluation, and treatment of alcoholism, drug abuse or **mental disorders** (including **substance related disorders**).

Residential treatment facility

An institution specifically licensed or certified as a **residential treatment facility** by applicable state or federal laws to provide for mental health or **substance related disorder** residential treatment programs.

Skilled nursing facility does not include institutions that provide only: • Minimal care • Custodial care • Ambulatory care • Part-time care It does not include institutions that primarily provide for the care and treatment of **mental disorders** or **substance related disorders**.	

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

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

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

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

Sources:

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

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

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

- NCQA standards (Aetna is NCQA Health Plan and Managed Behavioral Health Organization Accredited)

- Facility qualifications are reviewed to ensure facility meets Aetna's established requirements for organizational credentialing, including state licensing board, operating/certificate of occupancy, accreditation entity.

Definitions and evidentiary standards:

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

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

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

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

The participation criteria for providers and facilities are set forth in Aetna's Network Participation Criteria, linked in **A.**. Each provider must meet certain core criteria pertaining to qualifications, availability of services, office/facility environment, insurance and professional competence and conduct, as well as additional criteria apply according to the specific type of provider. An Aetna Medical Director or his or her physician-designee is authorized to make exceptions to Board certification, education, DEA certification, and hospital privileges requirements. The Credentialing & Performance Committee, which is comprised of participating providers in various specialties including behavioral health, is authorized to make final determinations with respect to exceptions to unencumbered license and professional competence and conduct requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The HMO product requires members to stay in-network, which is a service area where the HMO is licensed to operate. Geographic limitations inherent in an HMO product are not NQTLs imposed by the health plan. Rather, they are limitations set by the HMO's certificate of authority as dictated by applicable law (see, e.g., MD Health Gen. §§ 19-708(b)(9), 19-710(c)).

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

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

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

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

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

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

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

13. <u>Restrictions for Provider Specialty</u>

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

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

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

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

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

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

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

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

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

Med/Surg Benefits	MH/SUD Benefits
<u>Participating Provider and Facility Reimbursement</u> **Covered services:** Applies to all Med/Surg and MH/SUD non-prescription benefits delivered in-network **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 7-8 When we say "expense" in this general rule, we mean the **negotiated charge** for a **network provider**. **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). 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.	**<u>Participating Provider and Facility Reimbursement</u>** **Covered services:** Applies to all Med/Surg and MH/SUD non-prescription benefits delivered in-network **Plan language:** ➢ Section # 110 / Form # HI COC00110 05 / Page # 7-8 When we say "expense" in this general rule, we mean the **negotiated charge** for a **network provider**. **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). 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.

➢ Section # 10 / Form # HI HSOB 08 / Page # 2 How your cost share works • The **deductibles**, **copayments** and **coinsurance**, if any, listed in the schedule below are the amounts that you pay for **covered services**. These amounts are based on the **negotiated charge** for in-network and **allowable amount** for out-of-network services. See the *How your plan works* section of the certificate for more information. **Non-Participating Provider and Facility Reimbursement** **Covered services:** Emergency care and care unavailable in-network as described in the plan language below Aetna complies with MD Code, Health-General §§ 19-710(e) and 19-710.1), which requires payment of specified rates to non-participating hospitals, trauma physicians for trauma care rendered to a trauma patient in a trauma center, and any other health care provider for E&M and other services. **Plan language:** **HI MD COC 00110 05 page 3** **Who provides the care** **Network providers** We have contracted with **providers** in the service area to provide **covered services** to you. These **providers** make up the network for your plan. To get network benefits, you must use **network providers**. There are some exceptions:	➢ Section # 10 / Form # HI HSOB 08 / Page # 2 How your cost share works • The **deductibles**, **copayments** and **coinsurance**, if any, listed in the schedule below are the amounts that you pay for **covered services**. These amounts are based on the **negotiated charge** for in-network and **allowable amount** for out-of-network services. See the *How your plan works* section of the certificate for more information. **Non-Participating Provider and Facility Reimbursement** **Covered services:** Emergency care and care unavailable in-network as described in the plan language below Aetna complies with MD Code, Health-General §§ 19-710(e) and 19-710.1), which requires payment of specified rates to non-participating hospitals, trauma physicians for trauma care rendered to a trauma patient in a trauma center, and any other health care provider for E&M and other services. **Plan language:** **HI MD COC 00110 05 page 3** **Who provides the care** **Network providers** We have contracted with **providers** in the service area to provide **covered services** to you. These **providers** make up the network for your plan. To get network benefits, you must use **network providers**. There are some exceptions:

• **Emergency services** – see the description of **emergency services** in the *Coverage and exclusions* section. • Urgent care – see the description of urgent care in the *Coverage and exclusions* section. • Clinical trials – see the description of clinical trials in the *Coverage and exclusions* section. • **Network provider** not available without unreasonable delay/travel or does not have the training and expertise to treat your condition – You can get services from an **out-of-network provider**. You must request approval from us before you get the care. Contact us for assistance. • Use of a **provider** not in the network under continuity of care – see the description of continuity of care in the *Keeping a provider you go to now (continuity of care)* section below. • Transplants – see the description of transplant services in the *Coverage and exclusions* section.	• **Emergency services** – see the description of **emergency services** in the *Coverage and exclusions* section. • Urgent care – see the description of urgent care in the *Coverage and exclusions* section. • Clinical trials – see the description of clinical trials in the *Coverage and exclusions* section. • **Network provider** not available without unreasonable delay/travel or does not have the training and expertise to treat your condition – You can get services from an **out-of-network provider**. You must request approval from us before you get the care. Contact us for assistance. • Use of a **provider** not in the network under continuity of care – see the description of continuity of care in the *Keeping a provider you go to now (continuity of care)* section below. • Transplants – see the description of transplant services in the *Coverage and exclusions* section.

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

Participating Provider Reimbursement

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

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

Participating Facility Reimbursement

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

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

6. Market dynamics

Non-Participating Provider and Facility Reimbursement

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

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

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

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

Participating Provider Reimbursement

Sources and Processes:

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

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

Unit Cost [redacted]

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

No other sources were considered and rejected.

Participating Facility Reimbursement

Sources and Processes:

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

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

Unit Cost [redacted]

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

No other sources were considered and rejected.

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

Non-Participating Provider Reimbursement

State and federal law: State and federal laws prescribe how plans must reimburse OON providers for emergency services or when the member did not voluntarily use OON benefits. Aetna complies with MD Code, Health-General §§ 19-710(e) and 19-710.1, which requires payment of

specified rates to trauma physicians for trauma care rendered to a trauma patient in a trauma center and any other health care provider for E&M and other services. No sources were weighted more than another. No other sources were considered and rejected.

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

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

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

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

Participating Provider Reimbursement

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

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

(2) In contracting with providers, the Plan also uses comparable factors, strategies, processes and evidentiary standards for MH/SUD providers and M/S providers, both as written and in operation. [redacted]

Participating Facility Reimbursement

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

[redacted]

Non-Participating Provider and Facility Reimbursement

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

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

Aetna maintains one policy on rate development, [redacted] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf

MHPAEA Data Report for Calendar Year Ending December 31, 2021 (§15–144(f))						
Health Plan	**Aetna Health Inc. HMO**					
Benefit	**Classification**	**# of Authorization Requests Received**	**# of Authorization Requests Approved**	**# of Authorization Requests Denied**	**% Approved**	**% Denied**
Mental Health Benefits	**INN-Inpatient**	4	4	0	100%	0%
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	36	31	5	86%	14%
	INN-Outpatient-Office	4	4	0	100%	0%
	OON-Outpatient-Office	8	8	0	100%	0%
	INN-Outpatient-AllOther	8	8	0	100%	0%
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!
Substance Use Disorder Benefits	**INN-Inpatient**	6	6	0	100%	0%
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	0	0	0	#DIV/0!	#DIV/0!
	INN-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!

	INN-Outpatient-AllOther	8	4	4	50%	50%
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!
Medical /Surgical Benefits	**INN-Inpatient**	178	165	13	93%	7%
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	23	19	4	83%	17%
	INN-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	OON-Outpatient-Office	0	0	0	#DIV/0!	#DIV/0!
	INN-Outpatient-AllOther	435	323	102	74%	23%
	OON-Outpatient-AllOther	0	0	0	#DIV/0!	#DIV/0!

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

Health Plan	Aetna Health Inc. HMO	

Benefit	Classification	# of Claims Submitted	# of Claims Approved	# of Claims Denied	% Approved	% Denied
Mental Health Benefits	INN-Inpatient	78	63	15	81%	19%
	OON-Inpatient	1	0	1	0%	100%
	Emergency Services	64	63	1	98%	2%
	RX	2544	1753	791	68%	32%
	INN-Outpatient-Office	1335	1236	99	93%	7%
	OON-Outpatient-Office	40	0	40	0%	100%
	INN-Outpatient-AllOther	1434	1395	39	97%	3%
	OON-Outpatient-AllOther	13	0	13	0%	100%
Substance Use Disorder Benefits	INN-Inpatient	34	29	5	85%	15%
	OON-Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	48	47	1	98%	2%

	RX	93	44	49	50%	50%
	INN-Outpatient-Office	150	125	25	83%	17%
	OON-Outpatient-Office	14	0	14	0%	100%
	INN-Outpatient-AllOther	245	207	38	84%	16%
	OON-Outpatient-AllOther	13	0	13	0%	100%
Medical /Surgical Benefits	INN-Inpatient	1271	1050	221	83%	17%
	OON-Inpatient	4	0	4	0%	100%
	Emergency Services	1242	1155	87	93%	7%
	RX	14326	10168	4158	71%	29%
	INN-Outpatient-Office	13703	12886	817	94%	6%
	OON-Outpatient-Office	119	0	119	0%	100%
	INN-Outpatient-AllOther	18849	18087	762	96%	4%
	OON-Outpatient-AllOther	240	0	240	0%	100%