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Mental Health Parity Prescription Drug Benefit - Non-Quantitative Treatment Limitations

Aetna of Georgia, Advanced Control Formulary 2023 Pharmacy Benefit plan Analysis conducted December 2023

The contact for the client level CVS Caremark NQTL Comparative Analysis is the Aetna Account Team supporting Aetna of Georgia. The Pharmacy NQTL Comparative Analysis is developed by a multidisciplinary team from various CVS Caremark business and clinical support areas coordinated through the CVS Caremark Medical Affairs department.

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) is a federal law that generally prohibits group health plans and health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from imposing less-favorable benefit limitations on those benefits than on medical/surgical (MED/SURG) benefits. Benefit treatment limitations include quantitative treatment limits (QTLs), which are expressed numerically (such as a certain number of outpatient visit limits), and non-quantitative treatment limits (NQTLs), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage.

As part of a prescription drug benefit plan offering, CVS Caremark utilizes formulary and utilization management tools. These tools are essential to optimizing patient outcomes, reducing waste and unnecessary drug use, and providing cost-effective prescription drug benefit coverage. CVS Caremark considers the following formulary and UM tools as the prescription drug benefit NQTLs most commonly used in client plan offerings:

- Formulary tiering
- Prior Authorization (PA)
- Step Therapy (ST)
- Quantity Limits (QL)

The above formulary and UM tools, or prescription drug benefit NQTLs, are designed and applied consistently across all drugs and drug classes without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD conditions. Any coverage factors, processes, evidentiary standards, and development or implementation strategies applied to drugs used to treat MH/SUD conditions are comparable to, and are applied no more stringently than the coverage factors, evidentiary standards, processes, and development or implementation strategies used in applying the limitations to drugs used to treat MED/SURG conditions.

CVS Caremark has identified the following drug classes which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antidepressants
- Antianxiety agents
- Antipsychotics
- Hypnotics

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- Substance Use Disorder (SUD) agents

NQTL: Formulary tiering and design | Prescription Drugs

Formulary Tiering: A formulary is a list of drugs covered by a plan that offers prescription drug benefits. A formulary is sometimes referred to as a covered drug list. A tiered formulary is one that divides drugs into tiers that are ranked based on certain factors, including cost, whether the drug is generic or brand, or whether the product is considered preferred or non-preferred. The tiers on a formulary may determine the amount of cost share the member pays for a covered prescription drug. Formulary tier descriptions for this plan are listed below.

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

Attached is the 2023 Drug List Document:

https://fm.formularynavigator.com/FBO/41/2023_Advanced_Control_Plan_Aetna_.pdf

Factors considered when implementing formulary tiering and design:

Medical/Surgical	Mental Health / Substance Use Disorder
<p>The factors considered when establishing formulary tier designation for drugs used to treat MED/SURG conditions include:</p> <ul style="list-style-type: none">• Brand or generic status of the drug• Specialty drug status, if applicable for the plan• Impact of generic drugs or drugs designated to become available over-the-counter• Brand and generic pipeline• Line of business• Drug labeling approved by the U.S. Food and Drug Administration (FDA)• Availability of therapeutic alternatives• Utilization trends• Plan sponsor cost• Applicable manufacturer agreement• Potential impact on members	<p>The factors considered when establishing formulary tier designation for drugs used to treat MH/SUD conditions include:</p> <ul style="list-style-type: none">• Brand or generic status of the drug• Specialty drug status, if applicable for the plan• Impact of generic drugs or drugs designated to become available over-the-counter• Brand and generic pipeline• Line of business• Drug labeling approved by the U.S. Food and Drug Administration (FDA)• Availability of therapeutic alternatives• Utilization trends• Plan sponsor cost• Applicable manufacturer agreement• Potential impact on members

Definition of Factors:

- **Brand or generic status of the drug** – The brand or generic status of the drugs as designated by FDA. Generic drugs are typically placed on lower tiers.

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- **Specialty drug status, if applicable for the plan** – Specialty drugs are those that require special handling, special storage, or close clinical monitoring of the member. Due to the special handling of the drug or the drug's limited distribution, the prescription may need to be dispensed from a Specialty Pharmacy.
- **Drug pipeline for brands, generics, supplemental indications or drugs designated to become available over-the-counter** – Monitoring of drugs in development and visibility into new therapies and changes in treatment options which may be available in the future and may impact how formulary products are placed or covered on the formulary.
- **FDA approved uses** - Information on the drug's effects have been reviewed by the FDA, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population
- **Availability of therapeutic alternatives** – If there are alternative drugs available to treat the same condition, the more cost-effective alternative drug will typically be included in the lowest appropriate tier.
- **Line of business/Regulatory Requirements** –State and federal regulations may restrict/dictate how certain drugs should be covered on the formulary. Plans participating in government programs may have standard practices that direct how brands and generics are placed.
- **Utilization trends** – drug utilization reports help show use in order to assess impact of tiering on member access.
- **Plan sponsor costs** – cost to the plan can influence tier placement.
- **Manufacturer agreement** – agreements with drug manufacturers may include requirements for coverage on the formulary.
- **Potential impact on members** – Impact to member access may be considered when deciding to move a drug from a certain tier despite other factors, in order to promote medication adherence, for instance.

When the above factors are considered in the decision-making process for determining tier placement for drugs on the formulary, no more weight is given to one factor over another when determining tier placement for drugs used to treat MED/SURG conditions or for drugs used to treat MH/SUD conditions.

The sources and evidentiary standards used to apply the factors for formulary tiering and design:

Medical/Surgical	Mental Health/Substance Use Disorder
The sources and evidentiary standards considered when establishing formulary tier designation for drugs used in MED/SURG conditions include: <ul style="list-style-type: none">• FDA product labeling for approved uses and safety information. For example, if there is only one drug available on the market for a given indication, it would likely not be placed on the highest tier.	The sources and evidentiary standards considered when establishing formulary tier designation for drugs used in MH/SUD conditions include: <ul style="list-style-type: none">• FDA product labeling for approved uses and safety information. For example, if there is only one drug available on the market for a given indication, it would likely not be placed on the highest tier.

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Consensus documents and nationally sanctioned guidelines – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies Evidence-based reviews of peer-reviewed medical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references 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 Input from physicians practicing in the relevant clinical area 	<ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Consensus documents and nationally sanctioned guidelines – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies Evidence-based reviews of peer-reviewed medical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references 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 Input from physicians practicing in the relevant clinical area

As Written:

Processes and strategies applied when determining formulary tiering and design

Drug-tier designation takes into account a variety of factors, such as indications, clinical evidence (scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines), adverse event profile, available dosage forms, dosing frequency, generic competition, and adherence factors. The formulary selection process includes a comparison of similar drugs in terms of

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safety and effectiveness. In addition, drug and drug class appropriateness is taken into account when considering a drug for inclusion on a drug list.

During the process of determining tiering for a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine which tier may be appropriate for the drug.

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.

Drug products must first be deemed safe and effective by the P&T Committee before they are eligible for inclusion on a CVS Caremark Formulary or Drug List. The Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates the above-described factors when determining which drugs are placed in which tiers. The FRC makes recommendations based on such factors to the CVS Caremark National Pharmacy & Therapeutics (P&T) Committee for review and approval.

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.

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing formulary tier designation to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in developing tier designation applying to drugs used to treat MED/SURG conditions.

In Operation:

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The following table illustrates the number of drugs on each formulary tier within each drug category. The factors are applied in a comparable manner and no more stringently for drugs used to treat MH/SUD as for MED/SURG conditions.

Formulary Tiering Methodology:

The following is an analysis of the formulary tier designation:

- 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.
 - Preferred Tiers for the plan include: Tier 1 preferred generics, Tier 2 preferred brands, and Tier 4 preferred specialty

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

FORMULARY TIER DESCRIPTIONS:

- 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: AETNA of GEORGIA - Advanced Control Formulary - 2023								
Category		Results						
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred
	Drug Count by Tier	861	187	549	282	172	2,051	64.9%
	% of Drug Count per Tier	42.0%	9.1%	26.8%	13.7%	8.4%		
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred
	Drug Count by Tier	115	8	31	1	6	161	77.0%
	% of Drug Count per Tier	71.4%	5.0%	19.3%	0.6%	3.7%		
	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred

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Substance Use Disorder	Drug Count by Tier	17	1	7	1	1	27	70.4%
	% of Drug Count per Tier	63.0%	3.7%	25.9%	3.7%	3.7%		

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

- The Medical/Surgical category has 64.9% of the drugs at a preferred or lower-cost formulary tier.
- The Mental Health category has 77.0% of the drugs at a preferred or lower-cost formulary tier.
- The Substance Use Disorder category has 70.4% of the drugs at a preferred or lower-cost formulary tier.

Findings and Conclusion:

This comparative analysis demonstrates that formulary tiering is applied to MED/SURG drugs as well as MH/SUD drugs on this plan. As shown, the factors considered when determining formulary tier placement for drugs used to treat MH or SUD conditions are the same as those considered when determining formulary tier placement for drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when determining formulary tier placement for drugs in the MH/SUD category or for drugs in the MED/SURG category.

The processes and strategies for determining formulary tier placement for drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data demonstrates that formulary tier placement decisions for drugs in the MH/SUD drug classes and MED/SURG drug classes are based on similar factors. The testing and comparison of the percentage of drugs on preferred formulary tiers in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

% of MED/SURG drugs on preferred or lower-cost tiers:	64.9 %
% of MH drugs on preferred or lower-cost tiers:	77.0 %
% of SUD drugs on preferred or lower-cost tiers:	70.4 %

In conclusion, this analysis has demonstrated that in the determination of formulary tier placement as an NQTL, the factors, evidentiary standards, sources, processes, and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Prior Authorization | Prescription Drugs

Pharmacy prior authorization (PA): Prior authorization is a utilization management tool used to determine whether the intended use of a prescription drug meets a plan's medical necessity standards. Prior authorization is granted when member meets the plan's medical necessity requirements. When the criteria for prior authorization is not met, coverage for the drug is denied.

The document attached below is the Aetna of Georgia, Advanced Control Formulary - 2023 Pharmacy Utilization Management (UM) Program Drug List showing the drugs to which prior authorization has been applied:



AETNA-GA_ACF_202
3 Formulary NQTL D1

Factors considered when applying prior authorization to prescription drugs:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing pharmacy prior authorization for drugs used in MED/SURG include:</p> <ul style="list-style-type: none">• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability• Applicable lab values or other test results required for appropriate treatment• Appropriate medication uses for indications or conditions based on national guidelines• Use in appropriate patient populations• Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines• Potential for inappropriate or off-label use• Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met• Generic equivalent or alternative available on preferred tier• Multiple other dosage forms available on preferred tier• Reduce waste, unnecessary drug use, fraud, or abuse• Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet	<p>The factors considered when establishing pharmacy prior authorization for drugs used in MH/SUD include:</p> <ul style="list-style-type: none">• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability• Applicable lab values or other test results required for appropriate treatment• Appropriate medication uses for indications or conditions based on national guidelines• Use in appropriate patient populations• Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines• Potential for inappropriate or off-label use• Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met• Generic equivalent or alternative available on preferred tier• Multiple other dosage forms available on preferred tier• Reduce waste, unnecessary drug use, fraud, or abuse• Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet

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Medical/Surgical	Mental Health/Substance Use Disorder
therapy, case management, and other standard non-drug supportive therapies	therapy, case management, and other standard non-drug supportive therapies

Definition 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.
- **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
- **Appropriate medication uses for indications or conditions based on national guidelines; Use in appropriate patient populations** – National treatment guidelines and the FDA’s evaluation of these drugs determine their safety and efficacy for a particular disease or illness within the intended population, and define the drug’s use as initial therapy, second line therapy, or concurrent therapy. First line therapy refers to the initial recommended treatment for a disease or illness.
- **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
- **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.
- **Generic equivalent or alternative available on preferred tier; multiple other dosage forms available on preferred tier** – Other treatment options may be covered on a preferred tier, that do not have prior authorization or step therapy required but would be therapeutically equivalent.
- **Reduce waste, unnecessary drug use, fraud, or abuse** – practices that, directly or indirectly, result in unnecessary costs, overusing services.
- **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.

Sources and evidentiary standards used to apply prior authorization:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing prior authorization for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) 	<p>The sources and evidentiary standards considered when establishing prior authorization for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex 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 Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>Medicine (NEJM), Journal of Clinical Psychiatry</p> <ul style="list-style-type: none"> Approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

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Processes and strategies used in developing and applying prior authorization

Prior authorization programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include prior authorization programs to help identify the right drug, for the right member.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for prior authorization criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of prior authorization programs may include, but are not limited to: ensuring the drug is used in the appropriate place in therapy, drug has potential for use in unproven indications. Prior authorization programs and 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, prior authorization 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 and application of prior authorization is done without regard to a drug's formulary tier placement. CVS Caremark develops standard prior authorization programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize UM programs that are included with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drug is used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of prior authorization to drugs, no more weight is given to one factor over another in assessing the application of prior authorization to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorder conditions.

During the process of developing and assigning prior authorization to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when prior authorization may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible prior authorization programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.
- Clinical literature may provide further insight into the drug's place in therapy, or other concerns

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that may exist with this therapy.

- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of prior authorization criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, there is a particular safety concern with the new drug, or there are tests or lab values that need to be confirmed prior to starting therapy, or the drug is restricted to a specific population or place in therapy, then the new drug may have prior authorization applied to ensure the drug is used for the appropriate patients at the appropriate place in therapy.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling, if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying prior authorization to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying prior authorization to drugs used to treat MED/SURG conditions.

In Operation:

Methodology used in the testing and analysis of prior authorization:

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The following is an analysis of the pharmacy prior authorization:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with prior authorization in each category were summarized.
- Testing and comparisons of MH/SUD drugs with pharmacy prior authorization applying compared to MED/SURG drugs with pharmacy prior authorization applying at the drug class level were performed, showing:
 - Percentage of drugs with pharmacy prior authorization, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with pharmacy prior authorization, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of prior authorization between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step shows the comparison of the percentage of drugs subject to prior authorization at the MH, SUD and MED/SURG drug category levels. The next step was to display the prior authorization testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which prior authorization has been applied.

PRIOR AUTHORIZATION (PA) ANALYSIS
Plan: AETNA of GEORGIA - Advanced Control Formulary - 2023

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	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	2,051	161	27
PA Drug Count	768	31	0
% of Drugs with PA	37.4%	19.3%	0.0%

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 category and none of drugs in the SUD category compared to the MED/SURG category. Pharmacy prior authorization is applied to:

- 37.4% (768 out of 2,051) of the drugs in the Medical/Surgical category
- 19.3% (31 out of 161) of the drugs in the Mental Health category
- None of the drugs in the Substance Use Disorder category

The development of 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.

Testing results of the MH/SUD drug classes are below, showing the prior authorization applied when the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - Advanced Control Formulary - 2023				
MH/SUD DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
ANTIANKXIETY AGENTS		21	0	0%
ANTIDEPRESSANTS	> Patient safety concerns; unknown long-term safety > Evidence-based drug uses > Use in appropriate patient populations > Population age	44	16	36%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Evidence-based drug uses > Use in appropriate patient populations	52	7	13%
HYPNOTICS	> Use in appropriate patient populations > Potential for inappropriate use	14	7	50%
ADHD/STIMULANTS	> Patient safety concerns; unknown long-term safety > Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	30	1	3%
SUD		27	0	0%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The table below shows the testing results and factors that were considered for comparable MED/SURG drug classes. The following MED/SURG classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

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MED/SURG DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
HEPATITIS C	> Evidence-based drug uses > Use in appropriate patient populations	11	8	73%
ANTINEOPLASTICS	> Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	152	119	78%
OSTEOPOROSIS	> Patient safety concerns; unknown long-term safety > Use in appropriate patient populations	19	13	68%
ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	> Patient safety concerns; unknown long-term safety > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	5	4	80%
MULTIPLE SCLEROSIS	> Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	32	32	100%
FIBROMYALGIA	> Evidence-based drug uses > Use in appropriate patient populations > Potential for inappropriate use	2	2	100%
OPIOIDS	> Use in appropriate patient populations > Potential for inappropriate use > Potential for waste or unnecessary drug use	44	43	98%
ANTI-INFLAMMATORY	> Patient safety concerns; unknown long-term safety > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	58	32	55%
DERM - ANTIPSORIATICS	> Patient safety concerns; unknown long-term safety > Use in appropriate patient populations	19	17	89%
DERM - IMMUNOSUPPRESSANTS	> Evidence-based drug uses > Use in appropriate patient populations	2	2	100%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that prior authorization as an NQTL is assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan. As shown, the factors considered when applying prior authorization to drugs used to treat MH or SUD conditions are the same as those considered when applying prior authorization to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying prior authorization to drugs in the MH/SUD category or to drugs in the MED/SURG category.

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The processes and strategies for developing and applying prior authorization to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that prior authorization is applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, and is applied at lower rates in the MH/SUD drug classes, demonstrating no parity concerns with respect to application of prior authorization as an NQTL. The comparison of the percentage of drugs with prior authorization in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

<u>Prior Authorization in MH/SUD classes:</u>		<u>Prior Authorization in MED/SURG classes:</u>	
ANTIANXIETY	0%	HEPATITIS C	73%
ANTIDEPRESSANTS	36%	ANTINEOPLASTICS	78%
ANTIPSYCHOTICS	13%	OSTEOPOROSIS	68%
HYPNOTICS	50%	ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	80%
ADHD	3%	MULTIPLE SCLEROSIS	100%
SUD	0%	FIBROMYALGIA	100%
		OPIOIDS	98%
		ANTI-INFLAMMATORY	55%
		DERM – ANTIPSORIATICS	89%
		DERM – IMMUNOSUPPRESSANTS	100%

In conclusion, this analysis has demonstrated that in the application of prior authorization as an NQTL, the factors, evidentiary standards, sources, processes, and strategies, identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Step Therapy | Prescription Drugs

Pharmacy Step Therapy: Step therapy (ST) is a utilization management 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, and the intended use of the drug meets the plan's medical necessity standards. 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.

The document attached below is the Aetna of Georgia, Advanced Control Formulary 2023 Pharmacy Utilization Management (UM) Program NQTL Drug List showing the drugs to which step therapy has been applied.



AETNA-GA_ACF_202
3 Formulary NQTL D

Factors considered with the development of pharmacy step therapy:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing step therapy for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none">• 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	<p>The factors considered when establishing step therapy for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none">• 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

Definition 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**

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generics, used to treat the same condition: Other recommended more cost effective alternatives can be considered as supported by the resources described below, for the treatment of the condition or illness

- **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 standards of practice are maintained.
- **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.

Sources and evidentiary standards used to apply the factors in the development of pharmacy step therapy:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing step therapy for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) • Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • 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 • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • 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 	<p>The sources and evidentiary standards considered when establishing step therapy for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry • Approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • Appropriate clinical drug information from other sources as applicable – e.g., clinical guidance from agencies such as Centers for

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Medical/Surgical	Mental Health/Substance Use Disorder
<p>Centers for Medicare & Medicaid Services (CMS), FDA</p> <ul style="list-style-type: none"> • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), FDA</p> <ul style="list-style-type: none"> • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

As Written:

Processes and strategies used in developing and applying step therapy

Step therapy programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include step therapy programs to help identify the most cost effective drug for the member at the right place in therapy.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for step therapy criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of step therapy programs may include, but are not limited to: drug has potential for use in unproven indications, drug has potential for use as a first line therapy when other equally safe, and cost effective alternative drugs are available. Step therapy programs and 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, step therapy 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 and application of step therapy is done without regard to a drug's formulary tier placement. CVS Caremark develops standard step therapy programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize UM programs included with the formulary offering.

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Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drug is used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of step therapy to drugs, no more weight is given to one factor over another in assessing the application of step therapy to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorders conditions.

During the process of developing and assigning step therapy to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when step therapy may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible step therapy programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.
- Clinical literature may provide further insight into the drug's place in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of step therapy criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If all clinical attributes are essentially equivalent between the new drug and the existing drugs, then the determination may be made to apply step therapy to the new drug requiring a trial of a more cost effective drug that treats the same condition and has similar efficacy.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

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The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying step therapy to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying step therapy to drugs used to treat MED/SURG conditions.

In Operation:

Methodology used in the testing and analysis of pharmacy step therapy:

The following is an analysis of the pharmacy step therapy:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with step therapy in each category were summarized.
- Testing and comparisons of MH/SUD drugs with step therapy compared to MED/SURG drugs with step therapy at the drug class level were performed, showing:
 - Percentage of drugs with step therapy, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with step therapy, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that

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have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of step therapy between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step shows the comparison of the percentage of drugs subject to step therapy at the MH, SUD and MED/SURG drug category levels. The next step displays the step therapy testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which step therapy has been applied.

STEP THERAPY (ST) ANALYSIS			
Plan: AETNA of GEORGIA - Advanced Control Formulary - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	2,051	161	27
ST Drug Count	58	6	0
% of Drugs with ST	2.8%	3.7%	0.0%

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 small percentage of drugs in the MH and MED/SURG categories, and there is no step therapy applying to any drugs in the SUD category. Step therapy is applied to:

- 2.8% (58 out of 2,051) of the drugs in the Medical/Surgical category
- 3.7% (6 out of 161) 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.

Testing results of the MH/SUD drug classes are below, showing the step therapy applied when the factors were considered for each MH/SUD drug class:

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AETNA of GEORGIA - Advanced Control Formulary - 2023				
MH/SUD DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
ANTIANXIETY AGENTS		21	0	0%
ANTIDEPRESSANTS	> Promote the use of most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	44	2	5%
ANTIPSYCHOTICS/ANTIMANIC AGENTS		52	0	0%
HYPNOTICS	> Promote the use of most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	14	3	21%
ADHD/STIMULANTS	> Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier	30	1	3%
SUD		27	0	0%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The table below shows the testing results and factors that were considered for comparable MED/SURG drug class. The following MED/SURG drug classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - Advanced Control Formulary - 2023				
MED/SURG DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
ANTIDIABETICS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	68	14	21%
OSTEOPOROSIS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	19	5	26%
ANTIHYPERTENSIVES	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	51	1	2%
URINARY ANTISPASMODICS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	15	2	13%

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MED/SURG DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
BPH	<ul style="list-style-type: none"> > Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier 	7	1	14%
FIBROMYALGIA	<ul style="list-style-type: none"> > Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier 	2	2	100%
MIGRAINE PRODUCTS	<ul style="list-style-type: none"> > Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier 	36	19	53%
DERM - ANTIPSORIATICS	<ul style="list-style-type: none"> > Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier 	19	2	11%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that step therapy as an NQTL is assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan, and there is no step therapy applying to any drugs in the SUD drug classes. As shown, the factors considered when applying step therapy to drugs used to treat MH or SUD conditions are the same as those considered when applying step therapy to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying step therapy to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying step therapy to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that step therapy is applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, is applied at lower or comparable rates in the MH/SUD drug classes, and there is no step therapy applying to any drugs in the SUD drug classes. The comparison of the percentage of drugs with step therapy in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

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<u>Step Therapy in MH/SUD classes:</u>		<u>Step Therapy in MED/SURG classes:</u>	
ANTIANXIETY	76%	ANTIDIABETICS	21%
ANTIDEPRESSANTS	2%	OSTEOPOROSIS	26%
ANTIPSYCHOTICS	4%	ANTIHYPERTENSIVES	2%
HYPNOTICS	93%	URINARY ANTISPASMODICS	13%
ADHD	93%	BPH	14%
SUD	74%	FIBROMYALGIA	100%
		MIGRAINE PRODUCTS	53%
		DERM - ANTIPSORIATICS	11%

In conclusion, this analysis has demonstrated that in the application of step therapy as an NQTL, the factors, evidentiary standards, sources processes and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Quantity Limits | Prescription Drugs

Pharmacy Quantity Limits: Quantity Limits (QL) 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 quantity limits generally apply to both generic and brand drugs.

The document attached below is the Aetna of Georgia, Advanced Control Formulary 2023 Pharmacy Utilization Management (UM) Program Drug List showing the drugs to which quantity limits have been applied:



AETNA-GA_ACF_202
3 Formulary NQTL Di

Factors considered when applying quantity limits:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing pharmacy quantity limits for drugs used to treat MED/SURG conditions include:</p> <ul style="list-style-type: none">• Enhance patient safety<ul style="list-style-type: none">○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA○ To promote appropriate drug dosing, including strength and frequency○ To prevent overutilization○ When abuse or misuse by the patient is possible○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain• Cost and cost effectiveness<ul style="list-style-type: none">○ Prevention of overutilization○ Discouragement of misuse and waste through dose efficiency quantity limits, which ensure that the appropriate tablet strength is utilized○ Lack of documented efficacy/unknown efficacy at higher doses• Discourage misuse, waste, and abuse<ul style="list-style-type: none">○ Maximum daily dosing or maximum	<p>The factors considered when establishing pharmacy quantity limits for drugs used to treat MH/SUD conditions include:</p> <ul style="list-style-type: none">• Enhance patient safety<ul style="list-style-type: none">○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA○ To promote appropriate drug dosing, including strength and frequency○ To prevent overutilization○ When abuse or misuse by the patient is possible○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain• Cost and cost effectiveness<ul style="list-style-type: none">○ Prevention of overutilization○ Discouragement of misuse and waste through dose efficiency quantity limits, which ensure that the appropriate tablet strength is utilized○ Lack of documented efficacy/unknown efficacy at higher doses• Discourage misuse, waste, and abuse<ul style="list-style-type: none">○ Maximum daily dosing or maximum

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Medical/Surgical	Mental Health/Substance Use Disorder
duration of use limits	duration of use limits

Definition 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
- **Cost and cost effectiveness:** 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. Excessive quantity is defined as a quantity that exceeds the recommended dosing regimen or the recommended duration of therapy.
- **Discourage misuse, waste, and abuse:** practices that, directly or indirectly, result in unnecessary costs, overusing services.

Sources and evidentiary standards considered with pharmacy quantity limits:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing quantity limits for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) • Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • 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 	<p>The sources and evidentiary standards considered when establishing quantity limits for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry • Approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD.

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<ul style="list-style-type: none"> Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

As Written:

Processes and strategies used in developing and applying quantity limits

Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period by the Aetna of Georgia, Advanced Control Formulary. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount of drug covered by the client, or the number of prescription claims allowed for the drug over a period of time. When a prescription claim exceeds the established limit for the drug, the claim will not adjudicate for coverage in the CVS Caremark claims 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.

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Quantity limit programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include quantity limit programs to allow the appropriate quantity and duration of a drug to be covered.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for quantity limit criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of quantity limit programs may include, but are not limited to: drug has potential for use in unproven indications, drug has potential for being prescribed in quantities exceeding the recommended dosing regimens or quantities. Quantity limit programs and 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, quantity limit criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

The decision to implement quantity limits 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. Development and application of quantity limits is done without regard to a drug's formulary tier placement. CVS Caremark develops standard quantity limit programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize the UM programs to include with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of quantity limits to drugs, no more weight is given to one factor over another in assessing the application of quantity limits to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorders conditions.

During the process of developing and assigning quantity limits to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when quantity limits may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible quantity limit programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.

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- Clinical literature may provide further insight into the drug's amount of use in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of quantity limit criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, the new drug is available in many different strengths, or does not have a defined recommended dose and can be used 'as needed', or may have potential for abuse or misuse, then that drug may have a quantity limit applied to ensure an appropriate amount is allowed per prescription.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling, if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying quantity limits to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying quantity limits to drugs used to treat MED/SURG conditions.

In Operation:

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Methodology used in testing and analysis for the quantity limits:

The following is an analysis of the pharmacy quantity limits:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with quantity limits in each category were summarized.
- Testing and comparisons of MH/SUD drugs with quantity limits compared to MED/SURG drugs with quantity limits at the drug class level were performed, showing:
 - Percentage of drugs with quantity limits, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with quantity limits, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of quantity limits between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step was to show the comparison of the percentage of drugs subject to quantity limits at the MH, SUD and MED/SURG category levels. The next step was to display the quantity limits testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which quantity limits have been applied.

QUANTITY LIMITS (QL) ANALYSIS

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Plan: AETNA of GEORGIA - Advanced Control Formulary - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	2,051	161	27
QL Drug Count	841	60	20
% of Drugs with QL	41.0%	37.3%	74.1%

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

- 41.0% (841 out of 2,051) of the drugs in the Medical/Surgical category.
- 37.3% (60 out of 161) of the drugs in the Mental Health category.
- 74.1% (20 out of 27) of the drugs in the Substance Use Disorder category.

While the data shows that 74.1% of the drugs in the SUD drug category have quantity limits compared to 41.0% in the MED/SURG drug category, that does not reflect the rate of quantity limits that is seen in each of the drug classes in the MED/SURG drug category. As described above under Quantity Limit Methodology, the MH and SUD drug categories include a limited number of drugs that are used to treat specific conditions considered as mental health or substance use disorder conditions. The MED/SURG drug category, however, encompasses drugs used to treat specific medical or surgical conditions, as well as all other products included in the pharmacy benefit that are not categorized as MH or SUD drug category. The products classified in the MED/SURG drug category also include drugs such as vaccines, vitamins, insulin syringes and needles, and antibiotics that are used for short-term treatment, which are not appropriate comparisons to the drugs that are used to treat 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 drug category results in a total that appears lower than it would be if it only included the drugs used to treat chronic conditions like HIV, hepatitis-C, and multiple sclerosis, for example.

The factors utilized when quantity limits were added in a given class are listed in the tables below, and are similar between the MH/SUD drug classes and MED/SURG drug classes. A review of the percentage of quantity limits at the drug class level, demonstrates the rate of application of quantity limits to drugs in the MH/SUD drug classes is lower than the rate in the MED/SURG drug classes, as seen below:

Quantity Limits in MH/SUD classes:		Quantity Limits in MED/SURG classes:	
ANTIANXIETY	76%	HIV	100%
ANTIDEPRESSANTS	2%	HEPATITIS C	100%
ANTIPSYCHOTICS	4%	ANTIEMETICS 5HT-3	100%
HYPNOTICS	93%	MULTIPLE SCLEROSIS	100%
ADHD	93%	OPIOIDS	98%
SUD	74%	MIGRAINE AGENTS	94%
		DERM - ANTIPSORIATICS	79%
		DERM - PHN	86%

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		IMMUNOSUPPRESSANTS	100%
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Testing results of the MH/SUD drug classes are below, showing the quantity limits applied after the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - Advanced Control Formulary - 2023				
MH/SUD DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
ANTIANKXIETY AGENTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	21	16	76%
ANTIDEPRESSANTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	44	1	2%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	52	2	4%
HYPNOTICS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	14	13	93%
ADHD/STIMULANTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	30	28	93%
SUD	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	27	20	74%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The SUD category represents a very small number of drugs, most of which are used to treat tobacco use and opioid use disorders. A number of the SUD drugs are also opioids themselves, and have a significant potential for abuse or misuse, suggesting the need for close monitoring. The antianxiety and hypnotics classes also contain controlled substances with potential for misuse and abuse. Chronic use of hypnotics 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. 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. Quantity limits have been placed on these drugs to align

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with treatment guidelines, as well as FDA dosing recommendations. Methadone used for SUD has quantity limits to comply with 21 CFR 1306.07(b) and (c).

The table below shows the testing results and factors that were considered for comparable MED/SURG drug classes. The following MED/SURG drug classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - Advanced Control Formulary - 2023				
MED/SURG DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
HIV	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	56	56	100%
HEPATITIS C	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	11	11	100%
ANTIEMETICS 5HT-3	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	9	9	100%
MULTIPLE SCLEROSIS	> Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	32	32	100%
OPIOIDS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	44	43	98%
MIGRAINE PRODUCTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	36	34	94%
DERM - ANTIPSORIATICS	> Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	19	15	79%
DERM - PHN	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	7	6	86%
IMMUNOSUPPRESSANTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	24	24	100%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

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Findings and Conclusion:

This comparative analysis conducted above demonstrates that quantity limits as an NQTL are assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan. As shown, the factors considered when applying quantity limits to drugs used to treat MH or SUD conditions are the same as those considered when applying the quantity limit NQTL to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying quantity limits to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying quantity limits to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that quantity limits are applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, are applied at lower or comparable rates and are applied no more stringently in the MH/SUD drug classes. The comparison of the percentage of drugs with quantity limits in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

<u>Quantity Limits in MH/SUD classes:</u>		<u>Quantity Limits in MED/SURG classes:</u>	
ANTIANXIETY	76%	HIV	100%
ANTIDEPRESSANTS	2%	HEPATITIS C	100%
ANTIPSYCHOTICS	4%	ANTIEMETICS 5HT-3	100%
HYPNOTICS	93%	MULTIPLE SCLEROSIS	100%
ADHD	93%	OPIOIDS	98%
SUD	74%	MIGRAINE AGENTS	94%
		DERM - ANTIPSORIATICS	79%
		DERM - PHN	86%
		IMMUNOSUPPRESSANTS	100%

In conclusion, this analysis has demonstrated that in the application of quantity limits as an NQTL, the factors, evidentiary standards, sources, processes, and strategies, identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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Mental Health Parity Prescription Drug Benefit - Non-Quantitative Treatment Limitations

Aetna of Georgia, Marketplace Exchange Formulary 2023 Pharmacy Benefit plan Analysis conducted December 2023

The contact for the client level CVS Caremark NQTL Comparative Analysis is the CVS Caremark Account Team supporting Aetna of Georgia. The Pharmacy NQTL Comparative Analysis is developed by a multidisciplinary team from various CVS Caremark business and clinical support areas coordinated through the CVS Caremark Medical Affairs department.

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) is a federal law that generally prohibits group health plans and health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from imposing less-favorable benefit limitations on those benefits than on medical/surgical (MED/SURG) benefits. Benefit treatment limitations include quantitative treatment limits (QTLs), which are expressed numerically (such as a certain number of outpatient visit limits), and non-quantitative treatment limits (NQTLs), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage.

As part of a prescription drug benefit plan offering, CVS Caremark utilizes formulary and utilization management tools. These tools are essential to optimizing patient outcomes, reducing waste and unnecessary drug use, and providing cost-effective prescription drug benefit coverage. CVS Caremark considers the following formulary and UM tools as the prescription drug benefit NQTLs used in client plan offerings:

- Formulary tiering
- Prior Authorization (PA)
- Step Therapy (ST)
- Quantity Limits (QL)

The above formulary and UM tools, or prescription drug benefit NQTLs, are designed and applied consistently across all drugs and drug classes without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD conditions. Any coverage factors, processes, evidentiary standards, and development or implementation strategies applied to drugs used to treat MH/SUD conditions are comparable to, and are applied no more stringently than the coverage factors, evidentiary standards, processes, and development or implementation strategies used in applying the limitations to drugs used to treat MED/SURG conditions.

CVS Caremark has identified the following drug classes which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- | | |
|---|-------------------|
| • Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants | • Antidepressants |
| • Antianxiety agents | • Antipsychotics |
| | • Hypnotics |

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- Substance Use Disorder (SUD) agents

NQTL: Formulary tiering and design | Prescription Drugs

Formulary Tiering: A formulary is a list of drugs covered by a plan that offers prescription drug benefits. A formulary is sometimes referred to as a covered drug list. A tiered formulary is one that divides drugs into tiers that are ranked based on certain factors, including cost, whether the drug is generic or brand, or whether the product is considered preferred or non-preferred. The tiers on a formulary may determine the amount of cost share the member pays for a covered prescription drug. Formulary tier descriptions for this plan are listed below.

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

Attached is the 2023 Drug List Document:

https://fm.formularynavigator.com/FBO/41/2023_Aetna_Health_Exchange_Plan.pdf

Factors considered when implementing formulary tiering and design:

Medical/Surgical	Mental Health / Substance Use Disorder
<p>The factors considered when establishing formulary tier designation for drugs used to treat MED/SURG conditions include:</p> <ul style="list-style-type: none">• Brand or generic status of the drug• Specialty drug status, if applicable for the plan• Impact of generic drugs or drugs designated to become available over-the-counter• Brand and generic pipeline• Line of business• Drug labeling approved by the U.S. Food and Drug Administration (FDA)• Availability of therapeutic alternatives• Utilization trends• Plan sponsor cost• Applicable manufacturer agreement• Potential impact on members	<p>The factors considered when establishing formulary tier designation for drugs used to treat MH/SUD conditions include:</p> <ul style="list-style-type: none">• Brand or generic status of the drug• Specialty drug status, if applicable for the plan• Impact of generic drugs or drugs designated to become available over-the-counter• Brand and generic pipeline• Line of business• Drug labeling approved by the U.S. Food and Drug Administration (FDA)• Availability of therapeutic alternatives• Utilization trends• Plan sponsor cost• Applicable manufacturer agreement• Potential impact on members

Definition of Factors:

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- **Brand or generic status of the drug** – The brand or generic status of the drugs as designated by FDA. Generic drugs are typically placed on lower tiers.
- **Specialty drug status, if applicable for the plan** – Specialty drugs are those that require special handling, special storage, or close clinical monitoring of the member. Due to the special handling of the drug or the drug's limited distribution, the prescription may need to be dispensed from a Specialty Pharmacy.
- **Drug pipeline for brands, generics, supplemental indications or drugs designated to become available over-the-counter** – Monitoring of drugs in development and visibility into new therapies and changes in treatment options which may be available in the future and may impact how formulary products are placed or covered on the formulary.
- **FDA approved uses** - Information on the drug's effects have been reviewed by the FDA, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population
- **Availability of therapeutic alternatives** – If there are alternative drugs available to treat the same condition, the more cost-effective alternative drug will typically be included in the lowest appropriate tier.
- **Line of business/Regulatory Requirements** – State and federal regulations may restrict/dictate how certain drugs should be covered on the formulary. Plans participating in government programs may have standard practices that direct how brands and generics are placed.
- **Utilization trends** – drug utilization reports help show use in order to assess impact of tiering on member access.
- **Plan sponsor costs** – cost to the plan can influence tier placement.
- **Manufacturer agreement** – agreements with drug manufacturers may include requirements for coverage on the formulary.
- **Potential impact on members** – Impact to member access may be considered when deciding to move a drug from a certain tier despite other factors, in order to promote medication adherence, for instance.

When the above factors are considered in the decision-making process for determining tier placement for drugs on the formulary, no more weight is given to one factor over another when determining tier placement for drugs used to treat MED/SURG conditions or for drugs used to treat MH/SUD conditions.

The sources and evidentiary standards used to apply the factors for formulary tiering and design:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing formulary tier designation for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information. For example, if there is only one drug available on the market for a 	<p>The sources and evidentiary standards considered when establishing formulary tier designation for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information. For example, if there is only one drug available on the market for a

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Medical/Surgical	Mental Health/Substance Use Disorder
<p>given indication, it would likely not be placed on the highest tier.</p> <ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Consensus documents and nationally sanctioned guidelines – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies Evidence-based reviews of peer-reviewed medical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references 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 Input from physicians practicing in the relevant clinical area 	<p>given indication, it would likely not be placed on the highest tier.</p> <ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Consensus documents and nationally sanctioned guidelines – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies Evidence-based reviews of peer-reviewed medical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references 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 Input from physicians practicing in the relevant clinical area

As Written:

Processes and strategies applied when determining formulary tiering and design

Drug-tier designation takes into account a variety of factors, such as indications, clinical evidence (scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice

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guidelines), adverse event profile, available dosage forms, dosing frequency, generic competition, and adherence factors. The formulary selection process includes a comparison of similar drugs in terms of safety and effectiveness. In addition, drug and drug class appropriateness is taken into account when considering a drug for inclusion on a drug list.

During the process of determining tiering for a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine which tier may be appropriate for the drug.

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.

Drug products must first be deemed safe and effective by the P&T Committee before they are eligible for inclusion on a CVS Caremark Formulary or Drug List. The Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates the above-described factors when determining which drugs are placed in which tiers. The FRC makes recommendations based on such factors to the CVS Caremark National Pharmacy & Therapeutics (P&T) Committee for review and approval.

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.

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing formulary tier designation to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in developing tier designation applying to drugs used to treat MED/SURG conditions.

In Operation:

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The following table illustrates the number of drugs on each formulary tier within each drug category. The factors are applied in a comparable manner and no more stringently for drugs used to treat MH/SUD as for MED/SURG conditions.

Formulary Tiering Methodology:

The following is an analysis of the formulary tier designation:

- 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.
 - Preferred Tiers for the plan include: Tier 0 ACA preventive drugs, Tier 1 generics, Tier 2 preferred brands, and Tier 4 specialty preferred brands

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

FORMULARY TIER DESCRIPTIONS:

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

FORMULARY TIERING ANALYSIS									
Plan: AETNA of GEORGIA - GA Exchange Formulary - 2023									
Category		Results							
Medical / Surgical	Medical / Surgical	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred
	Drug Count by Tier	77	670	121	375	155	342	1,740	58.8%
	% of Drug Count per Tier	4.4%	38.5%	7.0%	21.6%	8.9%	19.7%		
Mental Health	Mental Health	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred
	Drug Count by Tier	0	86	1	38	1	3	129	68.2%
	% of Drug Count per Tier	0.0%	66.7%	0.8%	29.5%	0.8%	2.3%		
Substance Use Disorder	Substance Use Disorder	Tier 0	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total Drugs	% Preferred
	Drug Count by Tier								

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Substance Use Disorder	Drug Count by Tier	11	10	0	1	1	0	23	95.7%
	% of Drug Count per Tier	47.8%	43.5%	0.0%	4.3%	4.3%	0.0%		

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 or lower cost-share formulary tiers in the MH and SUD drug categories, compared to the MED/SURG drug category.

- The Medical/Surgical category has 58.8% of the drugs at a preferred or lower-cost formulary tier.
- The Mental Health category has 68.2% of the drugs at a preferred or lower-cost formulary tier.
- The Substance Use Disorder category has 95.7% of the drugs at a preferred or lower-cost formulary tier.

Findings and Conclusion:

This comparative analysis demonstrates that formulary tiering is applied to MED/SURG drugs as well as MH/SUD drugs on this plan. As shown, the factors considered when determining formulary tier placement for drugs used to treat MH or SUD conditions are the same as those considered when determining formulary tier placement for drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when determining formulary tier placement for drugs in the MH/SUD category or for drugs in the MED/SURG category.

The processes and strategies for determining formulary tier placement for drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data demonstrates that formulary tier placement decisions for drugs in the MH/SUD drug classes and MED/SURG drug classes are based on similar factors. The testing and comparison of the percentage of drugs on preferred formulary tiers in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

% of MED/SURG drugs on preferred or lower-cost tiers:	58.8%
% of MH drugs on preferred or lower-cost tiers:	68.2%
% of SUD drugs on preferred or lower-cost tiers:	95.7%

In conclusion, this analysis has demonstrated that in the determination of formulary tier placement as an NQTL, the factors, evidentiary standards, sources, processes and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Prior Authorization | Prescription Drugs

Pharmacy prior authorization (PA): Prior authorization is a utilization management tool used to determine whether the intended use of a prescription drug meets a plan's medical necessity standards. Prior authorization is granted when member meets the plan's medical necessity requirements. When the criteria for prior authorization is not met, coverage for the drug is denied.

The document attached below is the Aetna of Georgia, Marketplace Exchange Formulary 2023 Pharmacy Utilization Management (UM) Program Drug List showing the drugs to which prior authorization has been applied:



AETNA-GA_EXCHAN
GE_2023 Formulary I

Factors considered when applying prior authorization to prescription drugs:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing pharmacy prior authorization for drugs used in MED/SURG include:</p> <ul style="list-style-type: none">• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability• Applicable lab values or other test results required for appropriate treatment• Appropriate medication uses for indications or conditions based on national guidelines• Use in appropriate patient populations• Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines• Potential for inappropriate or off-label use• Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met• Generic equivalent or alternative available on preferred tier• Multiple other dosage forms available on preferred tier• Reduce waste, unnecessary drug use, fraud, or abuse• Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet	<p>The factors considered when establishing pharmacy prior authorization for drugs used in MH/SUD include:</p> <ul style="list-style-type: none">• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability• Applicable lab values or other test results required for appropriate treatment• Appropriate medication uses for indications or conditions based on national guidelines• Use in appropriate patient populations• Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines• Potential for inappropriate or off-label use• Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met• Generic equivalent or alternative available on preferred tier• Multiple other dosage forms available on preferred tier• Reduce waste, unnecessary drug use, fraud, or abuse• Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet

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Medical/Surgical	Mental Health/Substance Use Disorder
therapy, case management, and other standard non-drug supportive therapies	therapy, case management, and other standard non-drug supportive therapies

Definition 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.
- **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
- **Appropriate medication uses for indications or conditions based on national guidelines; Use in appropriate patient populations** – National treatment guidelines and the FDA’s evaluation of these drugs determine their safety and efficacy for a particular disease or illness within the intended population, and define the drug’s use as initial therapy, second line therapy, or concurrent therapy. First line therapy refers to the initial recommended treatment for a disease or illness.
- **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
- **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.
- **Generic equivalent or alternative available on preferred tier; multiple other dosage forms available on preferred tier** – Other treatment options may be covered on a preferred tier, that do not have prior authorization or step therapy required but would be therapeutically equivalent.
- **Reduce waste, unnecessary drug use, fraud, or abuse** – practices that, directly or indirectly, result in unnecessary costs, overusing services.
- **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.

Sources and evidentiary standards used to apply prior authorization:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing prior authorization for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) 	<p>The sources and evidentiary standards considered when establishing prior authorization for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex 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 Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>Medicine (NEJM), Journal of Clinical Psychiatry</p> <ul style="list-style-type: none"> Approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

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As Written:

Processes and strategies used in developing and applying prior authorization

Prior authorization programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include prior authorization programs to help identify the right drug, for the right member.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for prior authorization criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of prior authorization programs may include, but are not limited to: ensuring the drug is used in the appropriate place in therapy, drug has potential for use in unproven indications. Prior authorization programs and 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, prior authorization 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 and application of prior authorization is done without regard to a drug's formulary tier placement. CVS Caremark develops standard prior authorization programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize UM programs that are included with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drug is used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of prior authorization to drugs, no more weight is given to one factor over another in assessing the application of prior authorization to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorder conditions.

During the process of developing and assigning prior authorization to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when prior authorization may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible prior authorization programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.

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- Cost effectiveness is reviewed relative to alternatives in the same class.
- Clinical literature may provide further insight into the drug's place in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of prior authorization criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, there is a particular safety concern with the new drug, or there are tests or lab values that need to be confirmed prior to starting therapy, or the drug is restricted to a specific population or place in therapy, then the new drug may have prior authorization applied to ensure the drug is used for the appropriate patients at the appropriate place in therapy.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling, if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying prior authorization to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying prior authorization to drugs used to treat MED/SURG conditions.

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In Operation:

Methodology used in the testing and analysis of prior authorization:

The following is an analysis of the pharmacy prior authorization:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with prior authorization in each category were summarized.
- Testing and comparisons of MH/SUD drugs with pharmacy prior authorization applying compared to MED/SURG drugs with pharmacy prior authorization applying at the drug class level were performed, showing:
 - Percentage of drugs with pharmacy prior authorization, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with pharmacy prior authorization, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of prior authorization between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step shows the comparison of the percentage of drugs subject to prior authorization at the MH, SUD and MED/SURG drug category levels. The next step was to display the prior authorization testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

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The following table shows the number of drugs in each drug category to which prior authorization has been applied.

PRIOR AUTHORIZATION (PA) ANALYSIS			
Plan: AETNA of GEORGIA - GA Exchange Formulary - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	1,740	129	23
PA Drug Count	732	29	1
% of Drugs with PA	42.1%	22.5%	4.3%

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

- 42.1% (732 out of 1,740) of the drugs in the Medical/Surgical category
- 22.5% (29 out of 129) of the drugs in the Mental Health category
- 4.3% (1 out of 23) of the drugs in the Substance Use Disorder category

The development of 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.

Testing results of the MH/SUD drug classes are below, showing the prior authorization applied when the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - GA Exchange Formulary - 2023				
MH/SUD DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
ANTIANKXIETY AGENTS	> Use in appropriate patient populations > Potential for waste or unnecessary drug use > Population age	18	3	17%
ANTIDEPRESSANTS	> Patient safety concerns; unknown long-term safety > Evidence-based drug uses > Use in appropriate patient populations > Population age	43	16	37%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Evidence-based drug uses > Use in appropriate patient populations	33	4	12%
HYPNOTICS	> Use in appropriate patient populations > Potential for inappropriate use	14	5	36%

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ADHD/STIMULANTS	<ul style="list-style-type: none"> > Patient safety concerns; unknown long-term safety > Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations 	21	1	5%
SUD	<ul style="list-style-type: none"> > Use in appropriate patient populations > Potential for inappropriate use > Requirement for additional treatment-supportive therapies 	23	1	4%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The table below shows the testing results and factors that were considered for comparable MED/SURG drug classes. The following MED/SURG classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - GA Exchange Formulary - 2023				
MED/SURG DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
HEPATITIS C	<ul style="list-style-type: none"> > Evidence-based drug uses > Use in appropriate patient populations 	20	18	90%
ANTINEOPLASTICS	<ul style="list-style-type: none"> > Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations 	149	127	85%
PANCREATIC ENZYMES	<ul style="list-style-type: none"> > Evidence-based drug uses > Use in appropriate patient populations 	4	4	100%
ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	<ul style="list-style-type: none"> > Patient safety concerns; unknown long-term safety > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations 	4	4	100%
MULTIPLE SCLEROSIS	<ul style="list-style-type: none"> > Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations 	36	36	100%
FIBROMYALGIA	<ul style="list-style-type: none"> > Evidence-based drug uses > Use in appropriate patient populations > Potential for inappropriate use 	2	2	100%
OPIOIDS	<ul style="list-style-type: none"> > Use in appropriate patient populations > Potential for inappropriate use > Potential for waste or unnecessary drug use 	32	31	97%
ANTI-INFLAMMATORY	<ul style="list-style-type: none"> > Patient safety concerns; unknown long-term safety > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations 	68	46	68%

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MED/SURG DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
MUSCULOSKELETAL THERAPY AGENTS	> Patient safety concerns; unknown long-term safety > Use in appropriate patient populations > Potential for inappropriate use > Population age	12	9	75%
DERM - ANTIPSORIATICS	> Patient safety concerns; unknown long-term safety > Use in appropriate patient populations	19	18	95%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that prior authorization as an NQTL is assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan. As shown, the factors considered when applying prior authorization to drugs used to treat MH or SUD conditions are the same as those considered when applying prior authorization to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying prior authorization to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying prior authorization to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that prior authorization is applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, and is applied at lower rates in the MH and SUD drug classes, demonstrating no parity concerns with respect to application of prior authorization as an NQTL. The comparison of the percentage of drugs with prior authorization in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

Prior Authorization in MH/SUD classes:		Prior Authorization in MED/SURG classes:	
ANTIANXIETY	17%	HEPATITIS C	90%
ANTIDEPRESSANTS	37%	ANTINEOPLASTICS	85%
ANTIPSYCHOTICS	12%	PANCREATIC ENZYMES	100%
HYPNOTICS	36%	ANTI-NARCOLEPTICS	100%
ADHD	5%	MULTIPLE SCLEROSIS	100%
SUD	4%	FIBROMYALGIA	100%
		OPIOIDS	97%
		ANTI-INFLAMMATORY	68%
		MUSCULOSKELETAL THERAPY AGENTS	75%
		DERM – ANTIPSORIATICS	95%

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In conclusion, this analysis has demonstrated that in the application of prior authorization as an NQTL, the factors, evidentiary standards, sources, processes, and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

NQTL: Step Therapy | Prescription Drugs

Pharmacy Step Therapy: Step therapy (ST) is a utilization management 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, and the intended use of the drug meets the plan's medical necessity standards. 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.

The document attached below is the Aetna of Georgia, Marketplace Exchange Formulary 2023 Pharmacy Utilization Management (UM) Program NQTL Drug List showing the drugs to which step therapy has been applied.



AETNA-GA_EXCHAN
GE_2023 Formulary I

Factors considered with the development of pharmacy step therapy:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing step therapy for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> 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 	<p>The factors considered when establishing step therapy for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> 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

Definition 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**

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entities, or availability of unique dosage forms; Availability of therapeutic alternatives, including generics, used to treat the same condition: Other recommended more cost effective alternatives can be considered as supported by the resources described below, for the treatment of the condition or illness

- **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 standards of practice are maintained.
- **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.

Sources and evidentiary standards used to apply the factors in the development of pharmacy step therapy:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing step therapy for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) • Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • 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 • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • Appropriate clinical drug information from other sources as applicable – e.g., clinical 	<p>The sources and evidentiary standards considered when establishing step therapy for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry • Approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • Appropriate clinical drug information from

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Medical/Surgical	Mental Health/Substance Use Disorder
<p>guidance from agencies such as Centers for Disease Control and Prevention (CDC), The Centers for Medicare & Medicaid Services (CMS), FDA</p> <ul style="list-style-type: none"> • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>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</p> <ul style="list-style-type: none"> • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

As Written:

Processes and strategies used in developing and applying step therapy

Step therapy programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include step therapy programs to help identify the most cost effective drug for the member at the right place in therapy.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for step therapy criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of step therapy programs may include, but are not limited to: drug has potential for use in unproven indications, drug has potential for use as a first line therapy when other equally safe, and cost effective alternative drugs are available. Step therapy programs and 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, step therapy 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 and application of step therapy is done without regard to a drug's formulary tier placement. CVS Caremark develops standard step therapy programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to

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include the standard UM program bundles along with a template formulary, add additional UM programs, or customize UM programs included with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drug is used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of step therapy to drugs, no more weight is given to one factor over another in assessing the application of step therapy to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorders conditions.

During the process of developing and assigning step therapy to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when step therapy may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible step therapy programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.
- Clinical literature may provide further insight into the drug's place in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of step therapy criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If all clinical attributes are essentially equivalent between the new drug and the existing drugs, then the determination may be made to apply step therapy to the new drug requiring a trial of a more cost effective drug that treats the same condition and has similar efficacy.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

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approved labeling). CVS Caremark develops standard step therapy programs, and a plan or client chooses which step therapy programs to include in the plan offering.

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying step therapy to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying step therapy to drugs used to treat MED/SURG conditions.

In Operation:

Methodology used in the testing and analysis of pharmacy step therapy:

The following is an analysis of the pharmacy step therapy:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with step therapy in each category were summarized.
- Testing and comparisons of MH/SUD drugs with step therapy compared to MED/SURG drugs with step therapy at the drug class level were performed, showing:
 - Percentage of drugs with step therapy, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with step therapy, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

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Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of step therapy between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step shows the comparison of the percentage of drugs subject to step therapy at the MH, SUD and MED/SURG drug category levels. The next step displays the step therapy testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which step therapy has been applied.

STEP THERAPY (ST) ANALYSIS			
Plan: AETNA of GEORGIA - GA Exchange Formulary - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	1,740	129	23
ST Drug Count	33	5	0
% of Drugs with ST	1.9%	3.9%	0.0%

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 small percentage of drugs in the MH and MED/SURG drug categories, and there is no step therapy applying to any drugs in the SUD drug category. Step therapy is applied to:

- 1.9% (33 out of 1,740) of the drugs in the Medical/Surgical category
- 3.9% (5 out of 129) 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.

Testing results of the MH/SUD drug classes are below, showing the step therapy applied when the factors were considered for each MH/SUD drug class:

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MH/SUD DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
ANTIANXIETY AGENTS		18	0	0%
ANTIDEPRESSANTS	> Promote the use of most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	43	4	9%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier	33	1	3%
HYPNOTICS		14	0	0%
ADHD/STIMULANTS		21	0	0%
SUD		23	0	0%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The table below shows the testing results and factors that were considered for comparable MED/SURG drug class. The following MED/SURG drug classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - GA Exchange Formulary - 2023				
MED/SURG DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
ANTIDIABETICS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	57	15	26%
OSTEOPOROSIS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	13	1	8%
NASAL AGENTS - SYSTEMIC AND TOPICAL	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	9	1	11%
BPH	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	7	1	14%

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MED/SURG DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
FIBROMYALGIA	<ul style="list-style-type: none"> > Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier 	2	2	100%
MIGRAINE PRODUCTS	<ul style="list-style-type: none"> > Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier 	19	3	16%
GOUT AGENTS	<ul style="list-style-type: none"> > Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier 	5	1	20%
ANTICONVULSANTS	<ul style="list-style-type: none"> > Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier 	57	2	4%
GLAUCOMA	<ul style="list-style-type: none"> > Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier 	15	1	7%
DERM - ANTIPSORIATICS	<ul style="list-style-type: none"> > Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier 	19	1	5%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that step therapy as an NQTL is assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan, and there is no step therapy applying to any drugs in the SUD drug classes. As shown, the factors considered when applying step therapy to drugs used to treat MH or SUD conditions are the same as those considered when applying step therapy to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying step therapy to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying step therapy to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

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The analysis of the formulary data at the drug class level demonstrates that step therapy is applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, is applied at lower or comparable rates and is applied no more stringently in the MH/SUD drug classes, and there is no step therapy applying to any drugs in the SUD drug classes. The comparison of the percentage of drugs with step therapy in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

<u>Step Therapy in MH/SUD classes:</u>		<u>Step Therapy in MED/SURG classes:</u>	
ANTIANXIETY	0%	ANTIDIABETICS	26%
ANTIDEPRESSANTS	9%	OSTEOPOROSIS	8%
ANTIPSYCHOTICS	3%	NASAL AGENTS	11%
HYPNOTICS	0%	BPH	14%
ADHD	0%	FIBROMYALGIA	100%
SUD	0%	MIGRAINE PRODUCTS	16%
		GOUT AGENTS	20%
		ANTICONSULTANTS	4%
		GLAUCOMA	7%
		DERM - ANTIPSORIATICS	5%

In conclusion, this analysis has demonstrated that in the application of step therapy as an NQTL, the factors, evidentiary standards, sources processes and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Quantity Limits | Prescription Drugs

Pharmacy Quantity Limits: Quantity Limits (QL) 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 quantity limits generally apply to both generic and brand drugs.

The document attached below is the Aetna of Georgia, Marketplace Exchange Formulary 2023 Pharmacy Utilization Management (UM) Program Drug List showing the drugs to which quantity limits have been applied:



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GE_2023 Formulary I

Factors considered when applying quantity limits:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing pharmacy quantity limits for drugs used to treat MED/SURG conditions include:</p> <ul style="list-style-type: none">• Enhance patient safety<ul style="list-style-type: none">○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA○ To promote appropriate drug dosing, including strength and frequency○ To prevent overutilization○ When abuse or misuse by the patient is possible○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain• Cost and cost effectiveness<ul style="list-style-type: none">○ Prevention of overutilization○ Discouragement of misuse and waste through dose efficiency quantity limits, which ensure that the appropriate tablet strength is utilized○ Lack of documented efficacy/unknown efficacy at higher doses• Discourage misuse, waste, and abuse	<p>The factors considered when establishing pharmacy quantity limits for drugs used to treat MH/SUD conditions include:</p> <ul style="list-style-type: none">• Enhance patient safety<ul style="list-style-type: none">○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA○ To promote appropriate drug dosing, including strength and frequency○ To prevent overutilization○ When abuse or misuse by the patient is possible○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain• Cost and cost effectiveness<ul style="list-style-type: none">○ Prevention of overutilization○ Discouragement of misuse and waste through dose efficiency quantity limits, which ensure that the appropriate tablet strength is utilized○ Lack of documented efficacy/unknown efficacy at higher doses• Discourage misuse, waste, and abuse

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Maximum daily dosing or maximum duration of use limits 	<ul style="list-style-type: none"> Maximum daily dosing or maximum duration of use limits

Definition 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
- **Cost and cost effectiveness:** 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. Excessive quantity is defined as a quantity that exceeds the recommended dosing regimen or the recommended duration of therapy.
- **Discourage misuse, waste, and abuse:** practices that, directly or indirectly, result in unnecessary costs, overusing services.

Sources and evidentiary standards considered with pharmacy quantity limits:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing quantity limits for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> FDA product labeling for approved uses and safety information Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex 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 	<p>The sources and evidentiary standards considered when establishing quantity limits for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> FDA product labeling for approved uses and safety information Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry Approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA)

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>guidelines for treating SUD.</p> <ul style="list-style-type: none"> Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

As Written:

Processes and strategies used in developing and applying quantity limits

Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period by the Aetna of Georgia, Marketplace Exchange Formulary. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount of drug covered by the client, or the number of prescription claims allowed for the drug over a period of time. When a prescription claim exceeds the established limit for the drug, the claim will not adjudicate for coverage in the CVS Caremark claims 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.

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Quantity limit programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include quantity limit programs to allow the appropriate quantity and duration of a drug to be covered.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for quantity limit criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of quantity limit programs may include, but are not limited to: drug has potential for use in unproven indications, drug has potential for being prescribed in quantities exceeding the recommended dosing regimens or quantities. Quantity limit programs and 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, quantity limit criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

The decision to implement quantity limits 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. Development and application of quantity limits is done without regard to a drug's formulary tier placement. CVS Caremark develops standard quantity limit programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize the UM programs to include with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of quantity limits to drugs, no more weight is given to one factor over another in assessing the application of quantity limits to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorders conditions.

During the process of developing and assigning quantity limits to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when quantity limits may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible quantity limit programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.

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- Clinical literature may provide further insight into the drug's amount of use in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of quantity limit criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, the new drug is available in many different strengths, or does not have a defined recommended dose and can be used 'as needed', or may have potential for abuse or misuse, then that drug may have a quantity limit applied to ensure an appropriate amount is allowed per prescription.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling, if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying quantity limits to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying quantity limits to drugs used to treat MED/SURG conditions.

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In Operation:

Methodology used in testing and analysis for the quantity limits:

The following is an analysis of the pharmacy quantity limits:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with quantity limits in each category were summarized.
- Testing and comparisons of MH/SUD drugs with quantity limits compared to MED/SURG drugs with quantity limits at the drug class level were performed, showing:
 - Percentage of drugs with quantity limits, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with quantity limits, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of quantity limits between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step was to show the comparison of the percentage of drugs subject to quantity limits at the MH, SUD and MED/SURG category levels. The next step was to display the quantity limits testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which quantity limits have been applied.

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QUANTITY LIMITS (QL) ANALYSIS			
Plan: AETNA of GEORGIA - GA Exchange Formulary - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	1,740	129	23
QL Drug Count	839	47	17
% of Drugs with QL	48.2%	36.4%	73.9%

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:

- 48.2% (839 out of 1,740) of the drugs in the Medical/Surgical category.
- 36.4% (47 out of 129) of the drugs in the Mental Health category.
- 73.9% (17 out of 23) of the drugs in the Substance Use Disorder category.

While the data shows that 73.9% of the drugs in the SUD drug category have quantity limits compared to 48.2% in the MED/SURG drug category, that does not reflect the rate of quantity limits that is seen in each of the drug classes in the MED/SURG drug category. As described above under Quantity Limit Methodology, the MH and SUD drug categories include a limited number of drugs that are used to treat specific conditions considered as mental health or substance use disorder conditions. The MED/SURG drug category, however, encompasses drugs used to treat specific medical or surgical conditions, as well as all other products included in the pharmacy benefit that are not categorized as MH or SUD drug category. The products classified in the MED/SURG drug category also include drugs such as vaccines, vitamins, insulin syringes and needles, and antibiotics that are used for short-term treatment, which are not appropriate comparisons to the drugs that are used to treat 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 drug category results in a total that appears lower than it would be if it only included the drugs used to treat chronic conditions like hepatitis C, HIV, multiple sclerosis for example.

The factors utilized when quantity limits were added in a given class are listed in the tables below, and are similar between the MH/SUD drug classes and MED/SURG drug classes. A review of the percentage of quantity limits at the drug class level, demonstrates the rate of application of quantity limits to drugs in the MH/SUD drug classes is comparable to the rate in the MED/SURG drug classes, as seen below:

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<u>Quantity Limits in MH/SUD classes:</u>		<u>Quantity Limits in MED/SURG classes:</u>	
ANTIANXIETY	67%	HIV	100%
ANTIDEPRESSANTS	7%	HEPATITIS C	100%
ANTIPSYCHOTICS	6%	NASAL AGENTS	89%
HYPNOTICS	71%	PPIs	100%
ADHD	95%	ANTIEMETICS 5HT-3	100%
SUD	74%	MULTIPLE SCLEROSIS	100%
		OPIOIDS	97%
		MIGRAINE PRODUCTS	89%
		IMMUNOSUPPRESSANTS	100%

Testing results of the MH/SUD drug classes are below, showing the quantity limits applied after the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - GA Exchange Formulary - 2023				
MH/SUD DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
ANTIANXIETY AGENTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	18	12	67%
ANTIDEPRESSANTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	43	3	7%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	33	2	6%
HYPNOTICS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	14	10	71%
ADHD/STIMULANTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	21	20	95%
SUD	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	23	17	74%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

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The SUD category represents a very small number of drugs, most of which are used to treat tobacco use and opioid use disorders. A number of the SUD drugs are also opioids themselves, and have a significant potential for abuse or misuse, suggesting the need for close monitoring. The antianxiety and hypnotics classes also contain controlled substances with potential for misuse and abuse. Chronic use of hypnotics for sleep disorders may 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. 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. Quantity limits have been placed on these drugs to align with treatment guidelines, as well as FDA dosing recommendations. Methadone used for SUD has quantity limits to comply with 21 CFR 1306.07(b) and (c).

The table below shows the testing results and factors that were considered for comparable MED/SURG drug classes. The following MED/SURG drug classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - GA Exchange Formulary - 2023				
MED/SURG DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
HIV	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	57	57	100%
HEPATITIS C	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	20	20	100%
NASAL AGENTS - SYSTEMIC AND TOPICAL	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Cost-effectiveness	9	8	89%
PPIs	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Cost-effectiveness	7	7	100%
ANTIEMETICS 5HT-3	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	5	5	100%
MULTIPLE SCLEROSIS	> Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	36	36	100%
OPIOIDS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	32	31	97%

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AETNA of GEORGIA - GA Exchange Formulary - 2023				
MED/SURG DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
MIGRAINE PRODUCTS	<ul style="list-style-type: none"> > Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness 	19	17	89%
IMMUNOSUPPRESSANTS	<ul style="list-style-type: none"> > Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness 	15	15	100%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that quantity limits as an NQTL are assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan. As shown, the factors considered when applying quantity limits to drugs used to treat MH or SUD conditions are the same as those considered when applying the quantity limit NQTL to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying quantity limits to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying quantity limits to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that quantity limits are applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, are applied at lower or comparable rates and are applied no more stringently in the MH/SUD drug classes. The comparison of the percentage of drugs with quantity limits in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

Quantity Limits in MH/SUD classes:		Quantity Limits in MED/SURG classes:	
ANTIANXIETY	67%	HIV	100%
ANTIDEPRESSANTS	7%	HEPATITIS C	100%
ANTIPSYCHOTICS	6%	NASAL AGENTS	89%
HYPNOTICS	71%	PPIs	100%
ADHD	95%	ANTIEMETICS 5HT-3	100%
SUD	74%	MULTIPLE SCLEROSIS	100%
		OPIOIDS	97%
		MIGRAINE PRODUCTS	89%
		IMMUNOSUPPRESSANTS	100%

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In conclusion, this analysis has demonstrated that in the application of quantity limits as an NQTL, the factors, evidentiary standards, sources, processes and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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Mental Health Parity Prescription Drug Benefit - Non-Quantitative Treatment Limitations

Aetna of Georgia, Standard Opt-Out Formulary with ACSF 2023 Pharmacy Benefit plan Analysis conducted December 2023

The contact for the client level CVS Caremark NQTL Comparative Analysis is the Aetna Account Team supporting Aetna of Georgia. The Pharmacy NQTL Comparative Analysis is developed by a multidisciplinary team from various CVS Caremark business and clinical support areas coordinated through the CVS Caremark Medical Affairs department.

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) is a federal law that generally prohibits group health plans and health insurance issuers that provide mental health or substance use disorder (MH/SUD) benefits from imposing less-favorable benefit limitations on those benefits than on medical/surgical (MED/SURG) benefits. Benefit treatment limitations include quantitative treatment limits (QTLs), which are expressed numerically (such as a certain number of outpatient visit limits), and non-quantitative treatment limits (NQTLs), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage.

As part of a prescription drug benefit plan offering, CVS Caremark utilizes formulary and utilization management tools. These tools are essential to optimizing patient outcomes, reducing waste and unnecessary drug use, and providing cost-effective prescription drug benefit coverage. CVS Caremark considers the following formulary and UM tools as the prescription drug benefit NQTLs most commonly used in client plan offerings:

- Formulary tiering
- Prior Authorization (PA)
- Step Therapy (ST)
- Quantity Limits (QL)

The above formulary and UM tools, or prescription drug benefit NQTLs, are designed and applied consistently across all drugs and drug classes without regard to whether a drug is generally prescribed for MED/SURG or MH/SUD conditions. Any coverage factors, processes, evidentiary standards, and development or implementation strategies applied to drugs used to treat MH/SUD conditions are comparable to, and are applied no more stringently than the coverage factors, evidentiary standards, processes, and development or implementation strategies used in applying the limitations to drugs used to treat MED/SURG conditions.

CVS Caremark has identified the following drug classes which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants

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- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

NQTL: Formulary tiering and design | Prescription Drugs

Formulary Tiering: A formulary is a list of drugs covered by a plan that offers prescription drug benefits. A formulary is sometimes referred to as a covered drug list. A tiered formulary is one that divides drugs into tiers that are ranked based on certain factors, including cost, whether the drug is generic or brand, or whether the product is considered preferred or non-preferred. The tiers on a formulary may determine the amount of cost share the member pays for a covered prescription drug. Formulary tier descriptions for this plan are listed below.

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

Attached is the 2023 Drug List Document:

https://fm.formularynavigator.com/FBO/41/2023_Standard_Opt_Out_Aetna.pdf

Factors considered when implementing formulary tiering and design:

Medical/Surgical	Mental Health / Substance Use Disorder
<p>The factors considered when establishing formulary tier designation for drugs used to treat MED/SURG conditions include:</p> <ul style="list-style-type: none">• Brand or generic status of the drug• Specialty drug status, if applicable for the plan• Impact of generic drugs or drugs designated to become available over-the-counter• Brand and generic pipeline• Line of business• Drug labeling approved by the U.S. Food and Drug Administration (FDA)• Availability of therapeutic alternatives• Utilization trends• Plan sponsor cost• Applicable manufacturer agreement• Potential impact on members	<p>The factors considered when establishing formulary tier designation for drugs used to treat MH/SUD conditions include:</p> <ul style="list-style-type: none">• Brand or generic status of the drug• Specialty drug status, if applicable for the plan• Impact of generic drugs or drugs designated to become available over-the-counter• Brand and generic pipeline• Line of business• Drug labeling approved by the U.S. Food and Drug Administration (FDA)• Availability of therapeutic alternatives• Utilization trends• Plan sponsor cost• Applicable manufacturer agreement• Potential impact on members

Definition of Factors:

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- **Brand or generic status of the drug** – The brand or generic status of the drugs as designated by FDA. Generic drugs are typically placed on lower tiers.
- **Specialty drug status, if applicable for the plan** – Specialty drugs are those that require special handling, special storage, or close clinical monitoring of the member. Due to the special handling of the drug or the drug's limited distribution, the prescription may need to be dispensed from a Specialty Pharmacy.
- **Drug pipeline for brands, generics, supplemental indications or drugs designated to become available over-the-counter** – Monitoring of drugs in development and visibility into new therapies and changes in treatment options which may be available in the future and may impact how formulary products are placed or covered on the formulary.
- **FDA approved uses** - Information on the drug's effects have been reviewed by the FDA, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population
- **Availability of therapeutic alternatives** – If there are alternative drugs available to treat the same condition, the more cost-effective alternative drug will typically be included in the lowest appropriate tier.
- **Line of business/Regulatory Requirements** – State and federal regulations may restrict/dictate how certain drugs should be covered on the formulary. Plans participating in government programs may have standard practices that direct how brands and generics are placed.
- **Utilization trends** – drug utilization reports help show use in order to assess impact of tiering on member access.
- **Plan sponsor costs** – cost to the plan can influence tier placement.
- **Manufacturer agreement** – agreements with drug manufacturers may include requirements for coverage on the formulary.
- **Potential impact on members** – Impact to member access may be considered when deciding to move a drug from a certain tier despite other factors, in order to promote medication adherence, for instance.

When the above factors are considered in the decision-making process for determining tier placement for drugs on the formulary, no more weight is given to one factor over another when determining tier placement for drugs used to treat MED/SURG conditions or for drugs used to treat MH/SUD conditions.

The sources and evidentiary standards used to apply the factors for formulary tiering and design:

Medical/Surgical	Mental Health/Substance Use Disorder
The sources and evidentiary standards considered when establishing formulary tier designation for drugs used in MED/SURG conditions include: <ul style="list-style-type: none">• FDA product labeling for approved uses and safety information. For example, if there is	The sources and evidentiary standards considered when establishing formulary tier designation for drugs used in MH/SUD conditions include: <ul style="list-style-type: none">• FDA product labeling for approved uses and safety information. For example, if there is

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Medical/Surgical	Mental Health/Substance Use Disorder
<p>only one drug available on the market for a given indication, it would likely not be placed on the highest tier.</p> <ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Consensus documents and nationally sanctioned guidelines – e.g., Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for treating COPD, American Diabetes Association (ADA) Guidelines for Diabetes Care Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies Evidence-based reviews of peer-reviewed medical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references 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 Input from physicians practicing in the relevant clinical area 	<p>only one drug available on the market for a given indication, it would likely not be placed on the highest tier.</p> <ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Consensus documents and nationally sanctioned guidelines – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. Publications of the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and other organizations or government agencies Evidence-based reviews of peer-reviewed medical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry Standards of care recommended by clinical literature, medical or pharmacy societies, standard clinical drug references 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 Input from physicians practicing in the relevant clinical area

As Written:

Processes and strategies applied when determining formulary tiering and design

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Drug-tier designation takes into account a variety of factors, such as indications, clinical evidence (scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines), adverse event profile, available dosage forms, dosing frequency, generic competition, and adherence factors. The formulary selection process includes a comparison of similar drugs in terms of safety and effectiveness. In addition, drug and drug class appropriateness is taken into account when considering a drug for inclusion on a drug list.

During the process of determining tiering for a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine which tier may be appropriate for the drug.

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.

Drug products must first be deemed safe and effective by the P&T Committee before they are eligible for inclusion on a CVS Caremark Formulary or Drug List. The Formulary Review Committee (FRC) is an internal CVS Caremark committee that evaluates the above-described factors when determining which drugs are placed in which tiers. The FRC makes recommendations based on such factors to the CVS Caremark National Pharmacy & Therapeutics (P&T) Committee for review and approval.

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.

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing formulary tier designation to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in developing tier designation applying to drugs used to treat MED/SURG conditions.

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In Operation:

The following table illustrates the number of drugs on each formulary tier within each drug category. The factors are applied in a comparable manner and no more stringently for drugs used to treat MH/SUD as for MED/SURG conditions.

Formulary Tiering Methodology:

The following is an analysis of the formulary tier designation:

- 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.
 - Preferred Tiers for the plan include: Tier 1 generics, Tier 2 preferred brands

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

FORMULARY TIER DESCRIPTIONS:

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

FORMULARY TIERING ANALYSIS						
Plan: AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023						
Category		Results				
Medical / Surgical	Medical / Surgical	Tier 1	Tier 2	Tier 3	Total Drugs	% Preferred
	Drug Count by Tier	1,131	469	854	2,454	65.2%
	% of Drug Count per Tier	46.1%	19.1%	34.8%		
Mental Health	Mental Health	Tier 1	Tier 2	Tier 3	Total Drugs	% Preferred
	Drug Count by Tier	130	18	43	191	77.5%
	% of Drug Count per Tier	68.1%	9.4%	22.5%		

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Substance Use Disorder	Substance Use Disorder	Tier 1	Tier 2	Tier 3	Total Drugs	% Preferred
	Drug Count by Tier	19	3	9	31	71.0%
	% of Drug Count per Tier	61.3%	9.7%	29.0%		

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

- The Medical/Surgical category has 65.2% of the drugs at a preferred or lower-cost formulary tier.
- The Mental Health category has 77.5% of the drugs at a preferred or lower-cost formulary tier.
- The Substance Use Disorder category has 71.0% of the drugs at a preferred or lower-cost formulary tier.

Findings and Conclusion:

This comparative analysis demonstrates that formulary tiering is applied to MED/SURG drugs as well as MH/SUD drugs on this plan. As shown, the factors considered when determining formulary tier placement for drugs used to treat MH or SUD conditions are the same as those considered when determining formulary tier placement for drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when determining formulary tier placement for drugs in the MH/SUD category or for drugs in the MED/SURG category.

The processes and strategies for determining formulary tier placement for drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data demonstrates that formulary tier placement decisions for drugs in the MH/SUD drug classes and MED/SURG drug classes are based on similar factors. The testing and comparison of the percentage of drugs on preferred formulary tiers in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

% of MED/SURG drugs on preferred or lower-cost tiers:	65.2 %
% of MH drugs on preferred or lower-cost tiers:	77.5 %
% of SUD drugs on preferred or lower-cost tiers:	71.0 %

In conclusion, this analysis has demonstrated that in the determination of formulary tier placement as an NQTL, the factors, evidentiary standards, sources, processes, and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Prior Authorization | Prescription Drugs

Pharmacy prior authorization (PA): Prior authorization is a utilization management tool used to determine whether the intended use of a prescription drug meets a plan's medical necessity standards. Prior authorization is granted when member meets the plan's medical necessity requirements. When the criteria for prior authorization is not met, coverage for the drug is denied.

The document attached below is the Aetna of Georgia, Standard Opt-Out Formulary with ACSF 2023 Pharmacy Utilization Management (UM) Program Drug List showing the drugs to which prior authorization has been applied:



AETNA-GA_SOO_20
23 Formulary NQTL I

Factors considered when applying prior authorization to prescription drugs:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing pharmacy prior authorization for drugs used in MED/SURG include:</p> <ul style="list-style-type: none">• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability• Applicable lab values or other test results required for appropriate treatment• Appropriate medication uses for indications or conditions based on national guidelines• Use in appropriate patient populations• Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines• Potential for inappropriate or off-label use• Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met• Generic equivalent or alternative available on preferred tier• Multiple other dosage forms available on preferred tier• Reduce waste, unnecessary drug use, fraud, or abuse• Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet	<p>The factors considered when establishing pharmacy prior authorization for drugs used in MH/SUD include:</p> <ul style="list-style-type: none">• Patient safety concerns exist with a drug or drug class; unknown long-term safety or durability• Applicable lab values or other test results required for appropriate treatment• Appropriate medication uses for indications or conditions based on national guidelines• Use in appropriate patient populations• Use limited to a specific population based on FDA-approved indications, standard clinical practice, and guidelines• Potential for inappropriate or off-label use• Opportunity for optimizing patient outcomes, to ensure treatment goals of the drug are being met• Generic equivalent or alternative available on preferred tier• Multiple other dosage forms available on preferred tier• Reduce waste, unnecessary drug use, fraud, or abuse• Requirement for additional treatment supportive therapies, including but not limited to behavioral counseling, diet

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Medical/Surgical	Mental Health/Substance Use Disorder
therapy, case management, and other standard non-drug supportive therapies	therapy, case management, and other standard non-drug supportive therapies

Definition 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.
- **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
- **Appropriate medication uses for indications or conditions based on national guidelines; Use in appropriate patient populations** – National treatment guidelines and the FDA’s evaluation of these drugs determine their safety and efficacy for a particular disease or illness within the intended population, and define the drug’s use as initial therapy, second line therapy, or concurrent therapy. First line therapy refers to the initial recommended treatment for a disease or illness.
- **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
- **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.
- **Generic equivalent or alternative available on preferred tier; multiple other dosage forms available on preferred tier** – Other treatment options may be covered on a preferred tier, that do not have prior authorization or step therapy required but would be therapeutically equivalent.
- **Reduce waste, unnecessary drug use, fraud, or abuse** – practices that, directly or indirectly, result in unnecessary costs, overusing services.
- **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.

Sources and evidentiary standards used to apply prior authorization:

Medical/Surgical	Mental Health/Substance Use Disorder
The sources and evidentiary standards considered when establishing prior authorization for drugs used in MED/SURG conditions include: <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical 	The sources and evidentiary standards considered when establishing prior authorization for drugs used in MH/SUD conditions include: <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of

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Medical/Surgical	Mental Health/Substance Use Disorder
<p>Association (JAMA), New England Journal of Medicine (NEJM)</p> <ul style="list-style-type: none"> Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex 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 Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>Medicine (NEJM), Journal of Clinical Psychiatry</p> <ul style="list-style-type: none"> Approved drug compendia, including American Hospital Formulary Service® Drug, Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD. Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

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Processes and strategies used in developing and applying prior authorization

Prior authorization programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include prior authorization programs to help identify the right drug, for the right member.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for prior authorization criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of prior authorization programs may include, but are not limited to: ensuring the drug is used in the appropriate place in therapy, drug has potential for use in unproven indications. Prior authorization programs and 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, prior authorization 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 and application of prior authorization is done without regard to a drug's formulary tier placement. CVS Caremark develops standard prior authorization programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize UM programs that are included with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drug is used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of prior authorization to drugs, no more weight is given to one factor over another in assessing the application of prior authorization to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorder conditions.

During the process of developing and assigning prior authorization to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when prior authorization may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible prior authorization programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.

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- Clinical literature may provide further insight into the drug's place in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of prior authorization criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, there is a particular safety concern with the new drug, or there are tests or lab values that need to be confirmed prior to starting therapy, or the drug is restricted to a specific population or place in therapy, then the new drug may have prior authorization applied to ensure the drug is used for the appropriate patients at the appropriate place in therapy.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling, if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying prior authorization to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying prior authorization to drugs used to treat MED/SURG conditions.

In Operation:

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Methodology used in the testing and analysis of prior authorization:

The following is an analysis of the pharmacy prior authorization:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with prior authorization in each category were summarized.
- Testing and comparisons of MH/SUD drugs with pharmacy prior authorization applying compared to MED/SURG drugs with pharmacy prior authorization applying at the drug class level were performed, showing:
 - Percentage of drugs with pharmacy prior authorization, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with pharmacy prior authorization, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of prior authorization between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step shows the comparison of the percentage of drugs subject to prior authorization at the MH, SUD and MED/SURG drug category levels. The next step was to display the prior authorization testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which prior authorization has been applied.

PRIOR AUTHORIZATION (PA) ANALYSIS

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Plan: AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	2,454	191	31
PA Drug Count	720	21	1
% of Drugs with PA	29.3%	11.0%	3.2%

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

- 29.3% (720 out of 2,454) of the drugs in the Medical/Surgical category
- 11.0% (21 out of 191) of the drugs in the Mental Health category
- 3.2% (1 out of 31) of the drugs in the Substance Use Disorder category

The development of 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.

Testing results of the MH/SUD drug classes are below, showing the prior authorization applied when the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MH/SUD DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
ANTI-ANXIETY AGENTS		21	0	0%
ANTIDEPRESSANTS	> Patient safety concerns; unknown long-term safety > Evidence-based drug uses > Use in appropriate patient populations	54	5	9%
ANTI-PSYCHOTICS/ANTI-MANIC AGENTS	> Evidence-based drug uses > Use in appropriate patient populations	59	9	15%
HYPNOTICS	> Use in appropriate patient populations > Potential for inappropriate use	17	7	41%
ADHD/STIMULANTS		40	0	0%
SUD	> Use in appropriate patient populations > Potential for inappropriate use > Requirement for additional treatment-supportive therapies	31	1	3%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The table below shows the testing results and factors that were considered for comparable MED/SURG drug classes. The following MED/SURG classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

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AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MED/SURG DRUG CLASSES WITH PA	Prior Authorization Factors	TOTAL Drug Count	Count of Drugs with PA	Percent of Drugs with PA
HEPATITIS C	> Evidence-based drug uses > Use in appropriate patient populations	11	8	73%
ANTINEOPLASTICS	> Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	155	127	82%
OSTEOPOROSIS	> Patient safety concerns; unknown long-term safety > Use in appropriate patient populations	16	10	63%
STATINS	> Use in appropriate patient populations > Potential for waste or unnecessary drug use	13	8	62%
ANTI-NARCOLEPSY/ANTI- OBESITY/ANOREXIANTS	> Patient safety concerns; unknown long-term safety > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	7	5	71%
MULTIPLE SCLEROSIS	> Evidence-based drug uses > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	32	32	100%
OPIOIDS	> Use in appropriate patient populations > Potential for inappropriate use > Potential for waste or unnecessary drug use	61	60	98%
ANTI-INFLAMMATORY	> Patient safety concerns; unknown long-term safety > Applicable lab values or other test results required for appropriate treatment > Use in appropriate patient populations	62	32	52%
DERM - ANTIPSORIATICS	> Patient safety concerns; unknown long-term safety > Use in appropriate patient populations	23	17	74%
DERM - IMMUNOSUPPRESSANTS	> Evidence-based drug uses > Use in appropriate patient populations	4	3	75%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that prior authorization as an NQTL is assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan. As shown, the factors considered when applying prior authorization to drugs used to treat MH or SUD conditions are the same as those considered when applying prior authorization to drugs used to treat MED/SURG conditions.

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The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying prior authorization to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying prior authorization to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that prior authorization is applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, and is applied at lower rates in the MH/SUD drug classes, and there is no prior authorization applying to drugs in the SUD category. The comparison of the percentage of drugs with prior authorization in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

<u>Prior Authorization in MH/SUD classes:</u>		<u>Prior Authorization in MED/SURG classes:</u>	
ANTIANXIETY	0%	HEPATITIS C	73%
ANTIDEPRESSANTS	9%	ANTINEOPLASTICS	82%
ANTIPSYCHOTICS	15%	OSTEOPOROSIS	63%
HYPNOTICS	41%	STATINS	62%
ADHD	0%	ANTI-NARCOLEPSY/ANTIOBESITY/ANOREXIANTS	71%
SUD	3%	MULTIPLE SCLEROSIS	100%
		OPIOIDS	98%
		ANTI-INFLAMMATORY	52%
		DERM – ANTIPSORIATICS	74%
		DERM – IMMUNOSUPPRESSANTS	75%

In conclusion, this analysis has demonstrated that in the application of prior authorization as an NQTL, the factors, evidentiary standards, sources, processes, and strategies, identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Step Therapy | Prescription Drugs

Pharmacy Step Therapy: Step therapy (ST) is a utilization management 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, and the intended use of the drug meets the plan's medical necessity standards. 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.

The document attached below is the Aetna of Georgia, Standard Opt-Out Formulary with ACSF 2023 Pharmacy Utilization Management (UM) Program NQTL Drug List showing the drugs to which step therapy has been applied.



AETNA-GA_SOO_20
23 Formulary NQTL I

Factors considered with the development of pharmacy step therapy:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing step therapy for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none">• 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	<p>The factors considered when establishing step therapy for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none">• 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

Definition of Factors

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- **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:** Other recommended more cost effective alternatives can be considered as supported by the resources described below, for the treatment of the condition or illness
- **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 standards of practice are maintained.
- **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.

Sources and evidentiary standards used to apply the factors in the development of pharmacy step therapy:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing step therapy for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) • Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • 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 • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 	<p>The sources and evidentiary standards considered when establishing step therapy for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> • FDA product labeling for approved uses and safety information • Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry • Approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex • Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for treating SUD.

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> • 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 • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<ul style="list-style-type: none"> • Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references • 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 • Comparison of similar drugs in terms of safety and efficacy • Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department • Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area • Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

As Written:

Processes and strategies used in developing and applying step therapy

Step therapy programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include step therapy programs to help identify the most cost effective drug for the member at the right place in therapy.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for step therapy criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of step therapy programs may include, but are not limited to: drug has potential for use in unproven indications, drug has potential for use as a first line therapy when other equally safe, and cost effective alternative drugs are available. Step therapy programs and criteria are

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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, step therapy 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 and application of step therapy is done without regard to a drug's formulary tier placement. CVS Caremark develops standard step therapy programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize UM programs included with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drug is used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of step therapy to drugs, no more weight is given to one factor over another in assessing the application of step therapy to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorders conditions.

During the process of developing and assigning step therapy to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when step therapy may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible step therapy programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.
- Cost effectiveness is reviewed relative to alternatives in the same class.
- Clinical literature may provide further insight into the drug's place in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of step therapy criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If all clinical attributes are essentially equivalent between the new drug and the existing drugs, then the determination may be made to apply step therapy to the new drug requiring a trial of a more cost effective drug that treats the same condition and has similar efficacy.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling if these situations can be effectively managed through a prior

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authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying step therapy to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying step therapy to drugs used to treat MED/SURG conditions.

In Operation:

Methodology used in the testing and analysis of pharmacy step therapy:

The following is an analysis of the pharmacy step therapy:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with step therapy in each category were summarized.
- Testing and comparisons of MH/SUD drugs with step therapy compared to MED/SURG drugs with step therapy at the drug class level were performed, showing:
 - Percentage of drugs with step therapy, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with step therapy, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

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For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of step therapy between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step shows the comparison of the percentage of drugs subject to step therapy at the MH, SUD and MED/SURG drug category levels. The next step displays the step therapy testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

The following table shows the number of drugs in each drug category to which step therapy has been applied.

STEP THERAPY (ST) ANALYSIS			
Plan: AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	2,454	191	31
ST Drug Count	30	14	0
% of Drugs with ST	1.2%	7.3%	0.0%

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 small percentage of drugs in the MH and MED/SURG categories, and there is no step therapy applying to any drugs in the SUD category. Step therapy is applied to:

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- 1.2% (30 out of 2,454) of the drugs in the Medical/Surgical category
- 7.3% (14 out of 191) 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.

Testing results of the MH/SUD drug classes are below, showing the step therapy applied when the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MH/SUD DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
ANTIANKXIETY AGENTS		21	0	0%
ANTIDEPRESSANTS	> Promote the use of most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	54	3	6%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier	59	7	12%
HYPNOTICS	> Promote the use of most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	17	4	24%
ADHD/STIMULANTS		40	0	0%
SUD		31	0	0%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The table below shows the testing results and factors that were considered for comparable MED/SURG drug class. The following MED/SURG drug classes are considered to be comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MED/SURG DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
OSTEOPOROSIS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	16	2	13%

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AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MED/SURG DRUG CLASSES WITH ST	Step Therapy Factors	TOTAL Drug Count	Count of Drugs with ST	Percent of Drugs with ST
ANTIHYPERTENSIVES	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	54	2	4%
STATINS	> Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier	13	6	46%
NASAL AGENTS - SYSTEMIC AND TOPICAL	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	14	5	36%
ANTIASTHMATIC AND BRONCHODILATOR AGENTS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	65	1	2%
URINARY ANTISPASMODICS	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	18	4	22%
BPH	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	8	1	13%
MIGRAINE PRODUCTS	> Promote the use of most cost-effective products in the therapeutic class > Multiple dosage forms available on a preferred tier > Generic equivalent or therapeutic alternative available on preferred tier	32	3	9%
GLAUCOMA	> Promote the use of the most cost-effective products in the therapeutic class > Generic equivalent or therapeutic alternative available on preferred tier	19	4	21%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that step therapy as an NQTL is assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan, and there is no step therapy applying to any drugs in the SUD drug classes. As shown, the factors considered when applying step

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therapy to drugs used to treat MH or SUD conditions are the same as those considered when applying step therapy to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying step therapy to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying step therapy to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that step therapy is applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, is applied at lower or comparable rates and is applied no more stringently in the MH/SUD drug classes, and there is no step therapy applying to any drugs in the SUD drug classes. The comparison of the percentage of drugs with step therapy in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

<u>Step Therapy in MH/SUD classes:</u>		<u>Step Therapy in MED/SURG classes:</u>	
ANTIANXIETY	0%	OSTEOPOROSIS	13%
ANTIDEPRESSANTS	6%	ANTIHYPERTENSIVES	4%
ANTIPSYCHOTICS	12%	STATINS	46%
HYPNOTICS	24%	NASAL AGENTS	36%
ADHD	0%	ANTIASTHMATIC AGENTS	2%
SUD	0%	URINARY ANTISPASMODICS	22%
		BPH	13%
		MIGRAINE PRODUCTS	9%
		GLAUCOMA	21%

In conclusion, this analysis has demonstrated that in the application of step therapy as an NQTL, the factors, evidentiary standards, sources processes and strategies identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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NQTL: Quantity Limits | Prescription Drugs

Pharmacy Quantity Limits: Quantity Limits (QL) 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 quantity limits generally apply to both generic and brand drugs.

The document attached below is the Aetna of Georgia, Standard Opt-Out Formulary with ACSF 2023 Pharmacy Utilization Management (UM) Program Drug List showing the drugs to which quantity limits have been applied:



AETNA-GA_SOO_20
23 Formulary NQTL I

Factors considered when applying quantity limits:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The factors considered when establishing pharmacy quantity limits for drugs used to treat MED/SURG conditions include:</p> <ul style="list-style-type: none">• Enhance patient safety<ul style="list-style-type: none">○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA○ To promote appropriate drug dosing, including strength and frequency○ To prevent overutilization○ When abuse or misuse by the patient is possible○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain• Cost and cost effectiveness<ul style="list-style-type: none">○ Prevention of overutilization○ Discouragement of misuse and waste through dose efficiency quantity limits, which ensure that the appropriate tablet strength is utilized○ Lack of documented efficacy/unknown efficacy at higher doses• Discourage misuse, waste, and abuse	<p>The factors considered when establishing pharmacy quantity limits for drugs used to treat MH/SUD conditions include:</p> <ul style="list-style-type: none">• Enhance patient safety<ul style="list-style-type: none">○ Potential for a drug to be prescribed in greater quantities and/or at a higher dose than deemed safe and effective by the FDA○ To promote appropriate drug dosing, including strength and frequency○ To prevent overutilization○ When abuse or misuse by the patient is possible○ For opioids and narcotics, when appropriate dosing and appropriate duration of use is based on treatment for acute or chronic pain• Cost and cost effectiveness<ul style="list-style-type: none">○ Prevention of overutilization○ Discouragement of misuse and waste through dose efficiency quantity limits, which ensure that the appropriate tablet strength is utilized○ Lack of documented efficacy/unknown efficacy at higher doses• Discourage misuse, waste, and abuse

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Maximum daily dosing or maximum duration of use limits 	<ul style="list-style-type: none"> Maximum daily dosing or maximum duration of use limits

Definition 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
- **Cost and cost effectiveness:** 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. Excessive quantity is defined as a quantity that exceeds the recommended dosing regimen or the recommended duration of therapy.
- **Discourage misuse, waste, and abuse:** practices that, directly or indirectly, result in unnecessary costs, overusing services.

Sources and evidentiary standards considered with pharmacy quantity limits:

Medical/Surgical	Mental Health/Substance Use Disorder
<p>The sources and evidentiary standards considered when establishing quantity limits for drugs used in MED/SURG conditions include:</p> <ul style="list-style-type: none"> FDA product labeling for approved uses and safety information Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM) Nationally recognized and approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex 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 	<p>The sources and evidentiary standards considered when establishing quantity limits for drugs used in MH/SUD conditions include:</p> <ul style="list-style-type: none"> FDA product labeling for approved uses and safety information Published peer-reviewed clinical literature – e.g., Journal of the American Medical Association (JAMA), New England Journal of Medicine (NEJM), Journal of Clinical Psychiatry Approved drug compendia, including American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex Drugdex Accepted clinical practice guidelines, consensus statements, or comparable publications – e.g., Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), American Psychiatric Association (APA) Guidelines for treating Depression, Substance Abuse and Mental Health Services Administration (SAMHSA)

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Medical/Surgical	Mental Health/Substance Use Disorder
<ul style="list-style-type: none"> Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee 	<p>guidelines for treating SUD.</p> <ul style="list-style-type: none"> Standards of care noted in clinical literature, medical or pharmacy societies, standard clinical drug references 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 Comparison of similar drugs in terms of safety and efficacy Annual review of UM criteria and clinical programs by internal pharmacists in the Clinical Development department and medical directors in the Medical Affairs department Review of any new criteria, updates, and annual review of utilization management criteria, and clinical program content by external clinical experts, who are physicians practicing in the relevant clinical area Review and approval of prior authorization coverage criteria for clinical appropriateness by the CVS Caremark National P&T Committee

As Written:

Processes and strategies used in developing and applying quantity limits

Quantity Limits establish a maximum quantity of certain medications that will be covered over a specified time period by the Aetna of Georgia, Standard Opt-Out Formulary with ACSF. The limit is expressed in terms of dose or quantity dispensed per prescription, dose or quantity dispensed per time period, the amount of drug covered by the client, or the number of prescription claims allowed for the drug over a period of time. When a prescription claim exceeds the established limit for the drug, the claim will not adjudicate for coverage in the CVS Caremark claims 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.

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Quantity limit programs are commonly applied to determine if the drug's use is within the coverage strategy of the plan's pharmacy benefit. Plans may include quantity limit programs to allow the appropriate quantity and duration of a drug to be covered.

The clinical pharmacists in the UM Development department use the factors, sources and evidentiary standards to understand the drug's place in therapy, and apply the drug information to derive clinical content for quantity limit criteria. This outcome is reviewed by internal clinical pharmacists, medical directors and external expert consultants.

Considerations for application of quantity limit programs may include, but are not limited to: drug has potential for use in unproven indications, drug has potential for being prescribed in quantities exceeding the recommended dosing regimens or quantities. Quantity limit programs and 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, quantity limit criteria developed for medications used in mental health conditions require the same levels of clinical evidence as those that are not used or indicated for mental health conditions.

The decision to implement quantity limits 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. Development and application of quantity limits is done without regard to a drug's formulary tier placement. CVS Caremark develops standard quantity limit programs independent of the formulary plans and the programs can be applied to the various template formulary offerings. A plan can choose to include the standard UM program bundles along with a template formulary, add additional UM programs, or customize the UM programs to include with the formulary offering.

Medically necessary drugs or products are those necessary to prevent, diagnose, manage or treat conditions that cause acute suffering, endanger life, result in illness or infirmity, interfere with the capacity for normal activity, or threaten some significant handicap. Medical necessity standards apply to all prescription drugs, without regard to whether the drugs are used to treat MED/SURG, MH or SUD conditions.

When using the above factors to support application of quantity limits to drugs, no more weight is given to one factor over another in assessing the application of quantity limits to drugs used to treat medical or surgical conditions or to drugs used to treat mental health or substance use disorders conditions.

During the process of developing and assigning quantity limits to a given drug, the above sources and evidentiary standards are reviewed to gather information about the drug as applicable, such as how it is used to treat the condition, side effects and safety profile, and how it compares to other drugs available to treat the same condition. These sources provide the background information that is used when considering the factors that determine when quantity limits may be appropriate for the drug. The process for when a new drug comes to market and is considered for possible quantity limit programs includes the following steps:

- The FDA labeling provides the UM development team with information around indication, dosing, efficacy, and safety concerns, if any.

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- Cost effectiveness is reviewed relative to alternatives in the same class.
- Clinical literature may provide further insight into the drug's amount of use in therapy, or other concerns that may exist with this therapy.
- There is variability in timing of when new drugs are included in national guidelines, but the drug would be included as part of that particular therapeutic class which may be recommended at a given point in therapy. Guidelines are also reviewed during annual review of quantity limit criteria to determine if recommendations have changed in the past year.
- All of this information is compared against existing drugs in the same class, or that are used to treat the same condition. If, for example, the new drug is available in many different strengths, or does not have a defined recommended dose and can be used 'as needed', or may have potential for abuse or misuse, then that drug may have a quantity limit applied to ensure an appropriate amount is allowed per prescription.

Coverage conditions take into consideration safety concerns in black box warnings and/or contraindications in the product labeling, if these situations can be effectively managed through a prior authorization process. Additional safety-related concerns may be addressed at the recommendation of the External Clinical Expert(s).

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

The P&T Committee is an external advisory body of experts composed of independent health care professionals including physicians and pharmacists, who have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Members are included on the P&T Committee on the basis of active involvement in clinical practice (patient care); in the academic, hospital or community setting; national recognition in their specialty; contributions to medical and/or pharmacy literature; and previous experience with pharmacy and therapeutics committees.

The P&T Committee ensures that each Formulary provides appropriate access to drugs that are included in broadly accepted treatment guidelines and are indicative of general best practices, and ensures that each Formulary does not discourage enrollment by any group of enrollees by reviewing appropriateness of coverage for a range of disease states and utilization management tools. The P&T Committee ensures that drugs for the treatment of mental health conditions and substance use disorders are not managed more restrictively than drugs for other disease states.

The processes and strategies for developing and applying quantity limits to drugs used to treat MH or SUD conditions do not differ from the processes and strategies used in applying quantity limits to drugs used to treat MED/SURG conditions.

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In Operation:

Methodology used in testing and analysis for the quantity limits:

The following is an analysis of the pharmacy quantity limits:

- Drugs were grouped into MH, SUD and MED/SURG categories.
- Drug Count was derived from: Generic Product Indicator (GPI 12) code, Brand/Generic Code, Dosage Form, Drug Name, and Route of Administration
- Counts and percentages of drugs with quantity limits in each category were summarized.
- Testing and comparisons of MH/SUD drugs with quantity limits compared to MED/SURG drugs with quantity limits at the drug class level were performed, showing:
 - Percentage of drugs with quantity limits, as well as the factors considered and applied, in each of the MH/SUD drug classes
 - Percentage of drugs with quantity limits, as well as the factors considered and applied, in each of the comparable MED/SURG drug classes

For this analysis, the following drug classes have been identified which contain drugs most commonly used to treat mental health and substance use disorder conditions under the Pharmacy Benefit:

- Attention Deficit/Hyperactivity Disorder (ADHD) agents/stimulants
- Antianxiety agents
- Antidepressants
- Antipsychotics
- Hypnotics
- Substance Use Disorder (SUD) agents

Testing and comparison of coverage parity was done at the drug class level so that therapeutic classes that are used to treat medical or surgical conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy, were compared against the specific universe of drug classes that are used for mental health and substance use disorder conditions. This comparison is demonstrated in the drug class comparison tables included as part of this analysis.

In the testing of quantity limits between drugs used for MH/SUD conditions and drugs used for MED/SURG conditions, the first step was to show the comparison of the percentage of drugs subject to quantity limits at the MH, SUD and MED/SURG category levels. The next step was to display the quantity limits testing results at the drug class level.

Notes on the comparability of the drugs in the analysis:

- The MH and SUD categories include drugs from a limited number of drug classes.
- The MED/SURG category, however, encompasses all other drugs to treat a myriad of disease states that are not otherwise grouped as MH or SUD.
- The MED/SURG category also includes vaccines, vitamins, insulin syringes and needles, which are part of the benefit but are not drugs, and therefore are not directly comparable to the drugs in the MH/SUD categories.

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The following table shows the number of drugs in each drug category to which quantity limits have been applied.

QUANTITY LIMITS (QL) ANALYSIS			
Plan: AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023			
	Medical / Surgical	Mental Health	Substance Use Disorder
TOTAL Drug Count	2,454	191	31
QL Drug Count	798	68	22
% of Drugs with QL	32.5%	35.6%	71.0%

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:

- 32.5% (798 out of 2,454) of the drugs in the Medical/Surgical category.
- 35.6% (68 out of 191) of the drugs in the Mental Health category.
- 71.0% (22 out of 31) of the drugs in the Substance Use Disorder category.

While the data shows that 71.0% of the drugs in the SUD drug category have quantity limits compared to 32.5% in the MED/SURG drug category, that does not reflect the rate of quantity limits that is seen in each of the drug classes in the MED/SURG drug category. As described above under Quantity Limit Methodology, the MH and SUD drug categories include a limited number of drugs that are used to treat specific conditions considered as mental health or substance use disorder conditions. The MED/SURG drug category, however, encompasses drugs used to treat specific medical or surgical conditions, as well as all other products included in the pharmacy benefit that are not categorized as MH or SUD drug category. The products classified in the MED/SURG drug category also include drugs such as vaccines, vitamins, insulin syringes and needles, and antibiotics that are used for short-term treatment, which are not appropriate comparisons to the drugs that are used to treat 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 drug category results in a total that appears lower than it would be if it only included the drugs used to treat chronic conditions like HIV, Hepatitis-C, and multiple sclerosis, for example.

The factors utilized when quantity limits were added in a given class are listed in the tables below, and are similar between the MH/SUD drug classes and MED/SURG drug classes. A review of the percentage of quantity limits at the drug class level, demonstrates the rate of application of quantity limits to drugs in the MH/SUD drug classes is lower than the rate in the MED/SURG drug classes, as seen below:

Quantity Limits in MH/SUD classes:	
ANTIANXIETY	76%
ANTIDEPRESSANTS	0%

Quantity Limits in MED/SURG classes:	
HIV	100%
HEPATITIS C	100%

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ANTIPSYCHOTICS	3%	ANTINEOPLASTICS	75%
HYPNOTICS	71%	PPIs	69%
ADHD	95%	ANTIEMETICS 5HT-3	89%
SUD	71%	MULTIPLE SCLEROSIS	100%
		OPIOIDS	98%
		DERM - PHN	88%
		IMMUNOSUPPRESSANTS	100%

Testing results of the MH/SUD drug classes are below, showing the quantity limits applied after the factors were considered for each MH/SUD drug class:

AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MH/SUD DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
ANTIANKXIETY AGENTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	21	16	76%
ANTIDEPRESSANTS		54	0	0%
ANTIPSYCHOTICS/ANTIMANIC AGENTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	59	2	3%
HYPNOTICS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	17	12	71%
ADHD/STIMULANTS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	40	38	95%
SUD	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	31	22	71%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

The SUD category represents a very small number of drugs, most of which are used to treat tobacco use and opioid use disorders. A number of the SUD drugs are also opioids themselves, and have a significant potential for abuse or misuse, suggesting the need for close monitoring. The antianxiety class also contains controlled substances with potential for misuse and abuse. Chronic use of hypnotics for sleep disorders may be a sign of underlying physical or psychiatric disorders, it is important to monitor their use to assess the need for further evaluation of the condition. The antianxiety and hypnotics classes also contain controlled substances with potential for misuse and abuse. Most of the drugs used to treat

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ADHD are schedule II controlled substances, which have the highest potential for abuse among FDA approved prescription drugs. Quantity limits have been placed on these drugs to align with treatment guidelines, as well as FDA dosing recommendations. Methadone used for SUD has quantity limits to comply with 21 CFR 1306.07(b) and (c).

The table below shows the testing results and factors that were considered for comparable MED/SURG drug classes. The following MED/SURG drug classes are comparable to MH/SUD drug classes because they are those used to treat conditions with similar or greater magnitude of the NQTL, that have need for long term or chronic therapy.

AETNA of GEORGIA - Standard Opt Out Formulary with ACSF - 2023				
MED/SURG DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
HIV	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	56	56	100%
HEPATITIS C	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	11	11	100%
ANTINEOPLASTICS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Cost-effectiveness	155	117	75%
PPIs	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Cost-effectiveness	16	11	69%
ANTIEMETICS 5HT-3	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses	9	8	89%
MULTIPLE SCLEROSIS	> Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse	32	32	100%
OPIOIDS	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	61	60	98%
DERM - PHN	> Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness	8	7	88%

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MED/SURG DRUG CLASSES WITH QL	Quantity Limit Factors	TOTAL Drug Count	Count of Drugs with QL	Percent of Drugs with QL
IMMUNOSUPPRESSANTS	<ul style="list-style-type: none"> > Potential for unsafe and ineffective dose escalation > Dose optimization > Unknown or lack of efficacy at higher doses > Potential for abuse or misuse > Cost-effectiveness 	25	25	100%

Note: Drugs with the NQTL in each class are found in the attached Formulary NQTL Drug List

Findings and Conclusion:

This comparative analysis conducted above demonstrates that quantity limits as an NQTL are assigned in the same manner to MED/SURG drugs as to MH/SUD drugs on this plan. As shown, the factors considered when applying quantity limits to drugs used to treat MH or SUD conditions are the same as those considered when applying the quantity limit NQTL to drugs used to treat MED/SURG conditions.

The same types of sources and evidentiary standards are used when considering those factors. No more weight is given to one factor or evidentiary standard over another when applying quantity limits to drugs in the MH/SUD category or to drugs in the MED/SURG category.

The processes and strategies for developing and applying quantity limits to drugs used to treat MH/SUD conditions do not differ from the processes and strategies for drugs used to treat MED/SURG conditions.

The analysis of the formulary data at the drug class level demonstrates that quantity limits are applied to drugs in the MH/SUD drug classes and MED/SURG drug classes based on similar factors, are applied at lower or comparable rates and are applied no more stringently in the MH/SUD drug classes. The comparison of the percentage of drugs with quantity limits in the MH/SUD and MED/SURG drug classes on this plan is summarized below:

Quantity Limits in MH/SUD classes:		Quantity Limits in MED/SURG classes:	
ANTIANXIETY	76%	HIV	100%
ANTIDEPRESSANTS	0%	HEPATITIS C	100%
ANTIPSYCHOTICS	3%	ANTINEOPLASTICS	75%
HYPNOTICS	71%	PPIs	69%
ADHD	95%	ANTIEMETICS 5HT-3	89%
SUD	71%	MULTIPLE SCLEROSIS	100%
		OPIOIDS	98%
		DERM - PHN	88%
		IMMUNOSUPPRESSANTS	100%

In conclusion, this analysis has demonstrated that in the application of quantity limits as an NQTL, the factors, evidentiary standards, sources, processes, and strategies, identified above, both as written and in operation, are applied no more stringently to drugs used for mental health or substance use disorder conditions than to drugs used for medical or surgical conditions.

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Fully Insured Mental Health Parity NQTL Analysis

The analysis below explains how Aetna’s various clinical management and network development policies, procedures, and practices comply with the non-quantitative treatment limitation (NQTL) requirements of the Mental Health Parity and Addiction Equity Act (“MHPAEA”). The analysis includes links to publicly available information concerning clinical policy and procedure including medical management, i.e.) medical necessity criteria and utilization management criteria as well as network development standards and procedures. This analysis is reviewed and updated periodically, but not less than annually. This analysis follows the NQTL analytical framework prescribed by federal MHPAEA regulators (i.e. “factors” and “sources”).

There is a variety of information discussed in the comparability analysis below that is memorialized in greater detail in various policies, procedures, reports, and other documents (“Supplemental Information”). Such Supplemental Information is available for your review upon request.

Non-quantitative Treatment Limitations (NQTLs)

In accordance with state and federal law, Aetna’s plans comply with the nonquantitative treatment limitation requirements of the Mental Health Parity and Addiction Equity Act (“MHPAEA”). Aetna utilizes comparable processes, strategies, evidentiary standards, and other factors to determine NQTL requirements, including medical management review requirements such as precertification, for all plan benefits, including behavioral health, substance use disorder, medical, and surgical treatments. Moreover, these determinants are applied equally and no more stringently to behavioral health and substance use disorder benefits than they are applied to medical and surgical benefits. More information on Aetna’s compliance with regard to the particular types of NQTLs is set forth below.

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

Service Definitions

In Network Inpatient (IP): Acute medical, psychiatric or substance use disorder services requiring an overnight stay at a designated place of service and within a network of providers established or recognized under a plan.

Out of Network Inpatient (IP): Acute medical, psychiatric or substance use disorder services requiring an overnight stay at a designated place of service by providers that do not participate in Aetna's network.

In Network Outpatient Office Visit (OP OV): Refers to services provided by a healthcare professional in such a manner that the predominant trait of the outpatient services is direct, personal interaction with the professional. Such interactions typically, but not exclusively, occur in a healthcare professional's office, with limited reliance on technological interventions and within a network of providers established or recognized under a plan.

Out of Network Outpatient Office Visit (OP OV): Refers to services provided by a healthcare professional in such a manner that the predominant trait of the outpatient services is direct, personal interaction with the professional. Such interactions typically, but not exclusively, occur in a healthcare professional's office, with limited reliance on technological interventions, and are delivered by providers that do not participate in Aetna's network.

In Network Outpatient All Other (OP AO): Refers to outpatient services provided by a healthcare professional in a manner that the predominant trait of the outpatient service is something other than direct, personal interaction with the professional. Examples include outpatient services that are primarily dependent on a technological test or device, that are characterized by some type of physical intervention (e.g., a surgery or other procedure), or where services are provided as part of an integrated program. Outpatient services in the "other" sub-classification may be delivered in a variety of settings, including a healthcare facility, the community and or the home and are provided within a network of providers established or recognized under a plan.

Out of Network Outpatient All Other (OP AO): Refers to outpatient services provided by a healthcare professional in a manner that the predominant trait of the outpatient service is something other than direct, personal interaction with the professional. Examples include outpatient services that are primarily dependent on a technological test or device, that are characterized by some type of physical intervention (e.g., a surgery or other procedure), or where services are provided as part of an integrated program. Outpatient services in the "other" sub-classification may be delivered in a variety of settings, including a healthcare facility, the community and or the home, and are delivered by providers that do not participate in Aetna's network.

Emergency Care: Services provided in response to a medical emergency or urgent condition as well as emergency medical transportation.

Prescription drugs: Formulary brand name, formulary generic or covered non-formulary medications that require a prescription and are mailed to, delivered to, or picked up by the patient or designee.

Medical versus MH/SUD benefits: In keeping with MHPAEA guidance, benefits that are provided for the treatment of Mental Health/Substance Use Disorder (MH/SUD) conditions, as those conditions are defined by the most recent version of the Diagnostic and Statistical Manual (DSM), are MH/SUD benefits. All other benefits are considered medical/surgical benefits.

NQTL Applicability Summary

Non-Quantitative Treatment Limitations	Is NQTL applied to Medical/Surgical benefits?	Is NQTL applied to Mental Health/Substance Use Disorder benefits?	Is NQTL applied to In Network Inpatient classification?	Is NQTL applied to Out of Network Inpatient classification?	Is NQTL applied to In Network Outpatient classification?	Is NQTL applied to Out of Network Outpatient classification?	Is NQTL applied to Emergency classification?	Is NQTL applied to Prescription classification?	Is NQTL applied to In Network Outpatient-Office subclassification?	Is NQTL applied to Out of Network Outpatient- Office subclassification?	Is NQTL applied to In Network Outpatient-All Other subclassification?	Is NQTL applied to Out of Network Outpatient-All Other subclassification?
Prior Authorization/Precertification	Yes	Yes	Yes	Yes	Subclassify	Subclassify	Yes (only for one medical/surgical benefit)	See separate Pharmacy NQTL comparability analysis	No	No	Yes	Yes
Concurrent Review	Yes	Yes	Yes	Yes	Subclassify	Subclassify	No		No	No	Yes	Yes
Retrospective Review	Yes	Yes	No	Yes	Subclassify	Subclassify	Yes (only for one medical/surgical benefit)		No	No	No	Yes
Medical Necessity Criteria	Yes	Yes	Yes	Yes	Subclassify	Subclassify	Yes		Yes	Yes	Yes	Yes
Sequenced Treatment	Yes	Yes	Yes	Yes	Subclassify	Subclassify	No		No	No	Yes	Yes
Treatment Plan requirement	Yes	Yes	No	No	Subclassify	Subclassify	No		No	No	Yes	Yes
Benefit Exclusion including for experimental and investigational purposes	Yes	Yes	Yes	Yes	Subclassify	Subclassify	Yes		Yes	Yes	Yes	Yes
Network Provider Reimbursement	Yes	Yes	Yes	No	Subclassify	Subclassify	Yes		Yes	No	Yes	No
Non-Participating Provider Reimbursement/ UCR Determination	Yes	Yes	No	Yes	Subclassify	Subclassify	Yes		No	Yes	No	Yes
Network Facility Reimbursement	Yes	Yes	Yes	No	Subclassify	Subclassify	Yes		Yes	No	Yes	No

Non-Participating Facility Reimbursement/UCR Determination	Yes	Yes	No	Yes	Subclassify	Subclassify	Yes		No	Yes	No	Yes
Plan Standards to Ensure Network Adequacy	Yes	Yes	Yes	No	Subclassify	Subclassify	Yes		Yes	No	Yes	No
Physician Credentialing/Admission Standards	Yes	Yes	Yes	No	Subclassify	Subclassify	Yes		Yes	No	Yes	No

*Consistent with the NQTL types identified in the Final Rules and recent guidance

Utilization Management (UM)

Services Subject to Precertification, Concurrent Review, or Retrospective Review

Precertification, Concurrent Review and Retrospective Review (“UM”) does not apply to any medical surgical or MH/SUD benefits in the Outpatient-Office Visit (In-network and Out of Network) Classification. UM applies to the medical/surgical benefit of Fixed-wing Aircraft Transport in the Emergency Classification. All MH/SUD and non-palliative medical/surgical benefits in the Inpatient Classification are subject to UM. UM applies to three MH/SUD Outpatient All Other benefits: Applied Behavior Analysis for a diagnosis of Autism Spectrum Disorder, Partial Hospitalization, and Transcranial Magnetic Stimulation. UM 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>

Factors, Sources, Methods and Stringency Precertification, Concurrent Review and Retrospective Review NQTLs

The following framework organizes the factors, sources, methods and analysis and stringency application applied to the procedures, services, devices, and therapies to which Precertification, Concurrent Review, and Retrospective Review NQTLs apply in the Outpatient-All Other benefit classification for in-network and out-of-network (INN, OON) A detailed analytical framework is not provided for the Inpatient benefit classification since the Precertification, Concurrent Review, and Retrospective Review NQTLs apply to all non-palliative procedures, services, devices, and therapies in this classification for both medical/surgical and MH/SUD.

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. See Appendix 3 for a summary of Precertification Committee composition. This Precertification Committee oversees Aetna’s NPL, which physicians, hospitals and other health care professionals use for all plans to determine when medical/surgical or MH/SUD precertification is needed or required for each benefit classification for INN services.

Precertification

Precertification occurs before inpatient admissions and select ambulatory procedures and outpatient services. Precertification applies to:

- Procedures and services on the Aetna Participating Provider Precertification List,
- Procedures and services on the Aetna Behavioral Health Precertification List, and
- Procedures and services that require precertification under the terms of the member's plan.

Please refer to most up-to date 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>

Analysis for the Addition of a Service to the NPL:

***PRECERTIFICATION FACTOR LIST APPLICABLE TO BOTH MEDICAL/SURGICAL AND MH/SUD BENEFITS:**

1. All medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL must meet one or more of the following review methodologies specific to each of the identified factors:
 - a. Cost-- Cost of treatment is satisfied when the average paid Medicare rate was at least \$150 for the service being considered (based on Aetna's national paid Medicare claims experience)
 - b. High cost growth -- 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 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 PMPM from the 2017 PMPM and then divide by the 2015 PMPM)
 - c. Variability in cost and practice is satisfied when internal claims data demonstrates that there is greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period AND

All medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL must meet both of the following review methodologies specific to each of the identified factors

2. There must be at least one evidenced-based criteria (EBC) available to assist clinicians with precertification decisions. EBC may be sourced from national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies, or criteria from professional associations AND
3. Administrative inability to apply Claims Rules (Claims Rules are automated claims system controls that decide if coverage criteria is met). A procedure, drug or technology cannot feasibly be managed by Claim Rules alone due to either subjectivity or complexity of criteria

*Note--as part of the intake completed for new services being added to the NPL, generally a forecasted ROI is produced (and such requirement is noted in the intake instructions). Such forecasted ROI helps mitigate the risk of a service satisfying the initial inclusion factors in year one but failing the retention framework in subsequent years. It is important to note that for both

the inclusion framework or retention framework for the NPL all factors are equally applicable to the consideration of a medical/surgical service or MH/SUD service such that the in-writing component of parity is satisfied.

Analysis for the Retention of a Service to the NPL:

- After the first year and annually thereafter, the ROI is calculated, and a decision is made to retain or remove from the NPL primarily based on the following:
 - ROI 3:1 or greater - retain
 - ROI 2 to 2.9:1 – NPL committee discussion of extenuating factors (see below)
 - ROI \leq 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) - committee discussion of extenuating factors (see below)
- * While ROI may be the primary factor used to determine retention of a service on the NPL, the NPL Committee may consider additional factors that concern the NPL Committee which are unrelated to medical cost (e.g. incorrect utilization, or need to retain services on list to make coverage determinations consistent with Aetna's Clinical Policy Bulletins)

- Extenuating factors:

Extenuating factors are qualitative or quantitative points of consideration that, based on the expertise of Aetna's NPL Committee, warrant additional consideration (beyond the ROI) in connection with the retention or removal of a service from the NPL. Such extenuating factors may include High-cost growth (as calculated using the methodology described in the inclusion section above), variability in practice or cost (as calculated using the methodology described in the inclusion section above), Safety, incidence of occurrence, incorrect utilization, consistency with Aetna's Clinical Policy Bulletins, and End-to-end staff and system support for efficient management.

INN Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/SUD				
See multiple services listed on NPL	<p>Applied Behavioral Analysis (ABA) for a diagnosis of Autism Spectrum Disorder</p> <p>Transcranial Magnetic Stimulation</p> <p>Partial Hospitalization (PHP)</p>	<p>Factors used in the development of the initiation of the precertification NQTL for outpatient / all other benefit classification are listed below.</p> <p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <ul style="list-style-type: none"> • Cost • High cost growth • Variability in costs, length of treatment, or overall number of services for treatment • Evidence-based criteria • A procedure, drug, or technology cannot feasibly be managed by claim rules alone due to either subjectivity or complexity of criteria 	<p>The processes, strategies, and evidentiary standards used to define the factors include the following:</p> <p>The methods and analysis used in the development of the precertification NQTL include:</p> <ul style="list-style-type: none"> • Review of Medicare rates • Internal claims database analysis • Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations such as: <ul style="list-style-type: none"> • Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Medicare Benefit Policy Manual • MCG guidelines • National Comprehensive Cancer Network (NCCN) guidelines (Category 1 and 2A recommendations) • American Society of Addiction Medicine (ASAM) Criteria; Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, most recent version 	<p>A review of Medicare paid per procedure rates demonstrate that all procedures, services, devices, and therapies added to the NPL in 2021 (i.e. select hip arthroscopy codes, select prosthetics lower limb codes, select spinal fusion codes, select vertebral corpectomy codes) met the cost threshold of \$150.</p> <p>Additionally, the evidence-based criteria factor and the factor related to the inability to manage the service through claims rule were satisfied.</p>	<p>As Written: MH/SUD and medical/surgical Precertification/Concurrent/and Retrospective Review all share the same definition in our standard Certificate of coverage. Additionally, Aetna maintains one set of utilization management (UM) policies that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application of utilization management (UM) through several initiatives:</p> <ul style="list-style-type: none"> • Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care. • Denial Rates: comparative rate of MH/SUD vs. medical/surgical denials due to precertification/concurrent reviews. Book of Business data will be formally

INN Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/SUD				
			<ul style="list-style-type: none">• Applied Behavior Analysis Medical Necessity Guide• InterQual guidelines (as required by contractual provisions)• The Level of Care Utilization System (LOCUS) & Children and Adolescent Level of Care Utilization System (CALOCUS)• Review of generally accepted national quality standards, i.e.) National Committee for Quality Assurance, NCQA• Internal claims system review. Review of claims systems capabilities with Head of Operations to validate system functionality.		<p>reviewed by the MHP Task Force at least annually.</p> <ul style="list-style-type: none">• Internal Quality Reviews and Inter-Rater Reliability assessments: Clinical denials due to precertification reviews are conducted randomly throughout the year by Aetna’s Clinical Services Team. The MHP Task Force will review the results of these audits at least annually.• Average length of stay (ALOS) reviews: comparative ALOS of MH/SUD vs. medical/surgical cases. Book of Business data will be formally reviewed by the MHP Task Force at least annually.• Complaints and appeals: Aetna’s National Quality Oversight Committee, NQOC tracks and reviews trend rates of complaints and appeals at least annually. The MHP Task Force will review the results of these reviews at least annually.• Annual surveys: Comparative analysis of (Consumer Assessment of Healthcare Providers and Systems (CAHPs) survey, Qualified Health Plan Enrollee Experience Survey, Aetna BH Practitioner Experience Survey, Aetna BH Provider (Facility) Experience Survey, Aetna BH Member Experience Survey, Physician Practice Survey and surveys• Review of NPL Committee Minutes

INN Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
		Factor specific detail			
		All medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL meet one or more of the following review methodologies specific to each of the identified factors:			
		Cost of treatment Cost of treatment is satisfied when the average paid Medicare rate was at least \$150 for the service being considered (based on Aetna's national paid Medicare claims experience)	Internal claims data		
		High cost growth High cost growth is satisfied when internal claims data demonstrates that the cost (per member per month) for the procedure, service, device, or therapy increased >10% in the most recent two-year period	Internal claims data	This factor was not relied on to add any service to the NPL in 2021.	

INN Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
		Variability in cost and practice Variability in cost and practice is satisfied when internal claims data demonstrates that there is greater than three-fold variability in cost per unit, overall length of treatment, or overall number of services per treatment for the procedure, service, device, or therapy in the most recent 12-month period	Internal claims data	This factor was not relied on to add any service to the NPL in 2021.	

INN Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
		All medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL meet both of the following review methodologies specific to each of the identified factors:			
		Evidence based criteria (EBC) There must be at least one EBC tool available to assist clinicians with precertification decisions. EBC may be sourced from national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies, or criteria from professional associations	Evidence-based guidelines and/or criteria exist for all medical/surgical and MH/SUD procedures, services, devices, and therapies subject to the precertification NQTL. Availability of EBC exists for all the services on the NPL (via Aetna Clinical Policy Bulletins (CPBs) (https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html) <ul style="list-style-type: none">Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Medicare Benefit Policy ManualMCG guidelinesNational Comprehensive Cancer Network NCCN) guidelines (Category 1 and 2A recommendations)InterQual guidelines (as required by contractual provisions)American Society of Addiction Medicine (ASAM) Criteria; Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, Third EditionThe Level of Care Utilization System (LOCUS) & Children and Adolescent Level of Care Utilization System (CALOCUS)		

INN Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
		Administrative inability to apply Claims Rules (Claims Rules are automated claims system controls that decide if coverage criteria is met) A procedure, drug or technology cannot feasibly be managed by Claim Rules alone due to either subjectivity or complexity of criteria	Internal claims system review. Review of claims systems capabilities with Head of Operations to validate system functionality.		

OON Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/SUD				
<p>All medical/surgical services on the Member Precertification List:</p> <p>Home health care</p> <p>Hospice (outpatient)</p> <p>Skilled nursing care</p> <p>Bariatric surgery (outpatient and inpatient)</p> <p>Infertility (done in Women's Health)</p>	<p>All MH/SUD services on the Member Precertification List:</p> <p>Applied Behavioral Analysis (ABA) for a diagnosis of Autism Spectrum Disorder</p> <p>Transcranial Magnetic Stimulation</p> <p>Partial Hospitalization (PHP)</p>	<p>Factors used in the development of the initiation of the precertification NQTL for outpatient / all other benefit classification are listed below.</p> <p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <ul style="list-style-type: none"> Frequency of services being administered on an OON basis <ul style="list-style-type: none"> There is no fixed quantitative standard applied; rather frequency of services being administered on an OON basis is a quantitative evaluation of OON utilization rates relative to other Outpatient All Other services. Duration of the typical course of treatment <ul style="list-style-type: none"> There is no fixed quantitative standard applied; rather duration of the typical course of treatment is a quantitative evaluation of duration of treatment data relative to other Outpatient All Other services. 	<p>The processes, strategies, and evidentiary standards used to define the factors include the following:</p> <p>The methods and analysis used in the development of the precertification NQTL include:</p> <ul style="list-style-type: none"> Internal claims database analysis. See Appendix 5 and 6 for Medical and BH OP All Other OON and Duration claims data 	<p>As it relates to medical/surgical out-of-network utilization and average visits per member data, the medical/surgical services on the out-of-network precertification list all have the highest out-of-network utilization and average visits per member per year numbers compared to other medical/surgical Outpatient All Other services that are not on the out-of-network precertification list (with slight exception of gastric bypass which has an average visits per member per year that is more in line with other medical/surgical Outpatient All Other benefits that are not on the out-of-network precertification list). See Medical OP All Other OON and Duration Data spreadsheet.</p> <p>As it relates to MH/SUD out-of-network utilization and average visits per member per year, the MH/SUD services on the out-of-network precertification list all have the highest average visits per member per year and all have significant out-of-network utilization compared to other MH/SUD All Other benefits not on the out-of-network precertification list. See BH OP All Other OON and Duration data spreadsheet.</p>	<p>As Written: MH/SUD and medical/surgical Precertification/Concurrent/and Retrospective Review all share the same definition in our standard Certificates of coverage. Additionally, Aetna maintains one set of UM policies that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application of the precertification NQTL through several initiatives:</p> <ul style="list-style-type: none"> Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care. Denial Rates: comparative rate of MH/SUD vs. medical/surgical denials due to precertification/concurrent reviews. Book of Business data will be formally

OON Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/SUD				
					<p>reviewed by the MHP Task Force at least annually.</p> <ul style="list-style-type: none">• Internal Quality Reviews and Inter-Rater Reliability assessments: Clinical denials due to precertification reviews are conducted randomly throughout the year by Aetna’s Clinical Services Team. The MHP Task Force will review the results of these audits at least annually.• Average length of stay (ALOS) reviews: comparative ALOS of MH/SUD vs. medical/surgical cases. Book of Business data will be formally reviewed by the MHP Task Force at least annually.• Complaints and appeals: Aetna’s National Quality Oversight Committee, NQOC tracks and reviews trend rates of complaints and appeals at least annually. The MHP Task Force will review the results of these reviews at least annually.• Annual surveys: Comparative analysis of (Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, Qualified Health Plan Enrollee Experience Survey, Aetna BH Practitioner Experience Survey, Aetna BH Provider (Facility) Experience Survey, Aetna BH Member Experience Survey, Physician Practice Survey and surveys

Concurrent Review

Concurrent review is a utilization review service performed by licensed healthcare professionals to evaluate the patient's care while in the hospital or while undergoing outpatient treatment. The intent 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.

All inpatient services, whether MH/SUD or medical/surgical, are subject to Concurrent Review; as such comparability analysis is not required for the Inpatient INN and OON classifications. Concurrent Review in the Outpatient-All Other INN and OON classifications, as further described below, is conducted for services listed on the National Precertification List or member precertification list (for OON) and for MH/SUD services on the Behavioral Health Precertification list or member precertification list. (See link for current precertification list: <https://www.aetna.com/health-care-professionals/precertification/precertification-lists.html>). Concurrent Review involves a review for continued medical necessity for dates of service beyond the initial precertification authorization and occurs with subsequent coverage requests so that no gaps in the authorization exist.

This means that staff reviews all dates of service that do not have a coverage determination with a subsequent request for an extension of services. The Concurrent Review process includes a review for medical necessity and for the appropriate level of care that meets the member's clinical needs. We use standardized clinical guidelines, monitor the member's progress, review for potential quality of care concerns, and ensure there is an adequate discharge plan in place. If medical necessity is not evident, the case is sent for review to a medical director who may call the attending physician for additional information before rendering a coverage determination. For medical/surgical care, additional units (e.g. days, sessions) of care are authorized based on the individual needs of the member (i.e. clinical judgement based on complexity and severity) guided by care guidelines (which in many cases prescribe care pathways, treatments and lengths of stay), by facility contract, and clinical criteria. For MH/SUD, clinical judgment guided by clinical criteria dictates the number of additional units of care that are authorized.

MH/SUD's use of clinical judgment guided by clinical criteria as the sole process/strategy for determinations of additional units of care authorized exceeds the expectations of "comparability" under NQTL testing. Clinical judgement, when applied with the appropriate stringency controls discussed below, is a strategy that is more favorable to members. The medical/surgical utilization management team similarly uses clinical judgement as a process/strategy; however, clinical judgement is further constrained by facility contract, and care guidelines (which in many cases prescribe care pathways, treatments and lengths of stay). For both BH and medical/surgical, "severity" and "complexity", as used within our UM policies, are determined primarily based on the clinical judgement of expert reviewers and informed by the member's medical history, clinician progress notes, and discharge plans.

Aetna relies on the following processes and strategies to ensure clinical judgement remains a process/strategy that exceeds the minimum requirements of Parity for MH/SUD concurrent review frequency determinations: comparison of denial rates and average length of stay, Internal Quality Reviews (IQR) and Inter-Rater Reliability (IRR) assessments, NCQA Health Plan Accreditation, and peer-to-peer clinical review.

It should be noted that Aetna's book of business comparative analysis of UM denials rates and average length of stays demonstrate that on scale, MH/SUD benefits historically have significantly fewer denials per 1,000 admissions and longer average lengths of stays than medical surgical comparable benefits.

Regarding IQR and IRR review, among other things, the intent is to identify both strengths and opportunities for improvement in the delivery of UM services, and to measure compliance with National Committee of Quality Assurance (NCQA) File Review standards (which evaluate both BH and medical surgical UM practice and are designated as "must pass" for recertification). A

random sample of UM denials, which includes all lines of business and product types, is conducted periodically. The goal for each audit is an aggregate audit score of at least 95%. An NCQA File Review tool is used to complete the audits. Quantitative and qualitative feedback is provided by the audit process to individual UM reviewers.

The Medical Director Internal Quality Review is a process for re-adjudication of a claim in situations where a Senior Medical Director (SMD) or Medical Director (MD) auditor disagrees with a medical necessity determination made by a Medical Director (MD) and/or Physician Advisor (PA) and/or Clinician Advisor (CA).

Aetna’s Peer-to-peer review process seeks to decrease the risk of inconsistencies in the operationalization of UM policies by allowing a treating practitioner, a clinician on behalf of the treating practitioner or a facility designated physician to discuss a clinical denial of coverage determination with a peer reviewer or behavioral health consultant psychiatrist/psychologist to mitigate the risk of operational disparities based on differences in the quantity/quality of written documentation the treating practitioner may provide.

Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/ Surgical	MH/SUD				
OUTPATIENT-ALL OTHER					
All medical/ surgical outpatient all other services/ procedures on the National Precertification List (NPL)	All MH/SUD outpatient all other services/ procedures on the Behavioral Health Precertification List	Refer to Factors for Precertification NQTL	Refer to Sources for Precertification NQTL	Refer to Comparability Analysis for Precertification NQTL	Refer to Stringency Analysis for Precertification NQTL

Retrospective Review

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. Retrospective review is utilized for 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. Retrospective Review is only used In Network for emergency inpatient admissions for participating facilities that have a deviation for late notification on the Late Notification Deviation list or a facility that is on the Internal or External Disaster Deviation List. The Late Notification Deviation list is a list of participating facilities that as part of their vendor contract they are eligible for retro review for emergent admits when they fail to notify us on the front end. The Internal and External disaster list is when there are disasters in certain States, such as hurricanes, that the facilities are allowed to request retro review for the specific timeframes noted on the deviation list since the facilities are not required to notify us on the front end. Both such lists are a benefit to in-network providers as the failure to precertify services generally results in an administrative denial with no recourse for the facility to balance bill the member.

Services/procedures to which the NQTL applies INN		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/ Surgical	MH/SUD				
All medical/surgical inpatient and outpatient all other services/procedures on the Member Precertification List that were not precertified	All MH/SUD inpatient and outpatient all other services/procedures on the Behavioral Health the Member Precertification List that were not precertified	Refer to Factors for Precertification NQTL	Refer to Sources for Precertification NQTL	Refer to Comparability Analysis for Precertification NQTL	Refer to Stringency Analysis for Precertification NQTL

Additional UM Analysis		
Item	Medical/Surgical	MH/SUD
Denial Rate & Average Length of Stay (ALOS) Stringency Analysis	See Appendix 7 2021 MHP Utilization Report	
Who is responsible for UM reviews and general UM review process	<p>An initial clinician reviewer (most commonly a registered nurse for med/surg cases or a licensed clinical social worker or licensed professional counselor for MH/SUD) initially reviews authorization requests. These clinicians are appropriately-licensed.</p> <p>If the initial clinician reviewer determines the documentation submitted supports that the patient meets established clinical criteria for the requested service, an approval (authorization) is entered in Utilization Management system, so that when the reimbursement claim is submitted, the claim processor knows the service was approved.</p> <p>If the initial clinician reviewer does not believe the documentation provided establishes that the patient and proposed service meet established clinical criteria, the clinician reviewer sends the review/denial to an Aetna Medical Director for confirmation and a final coverage determination. The Medical Director reviews:</p> <ul style="list-style-type: none"> • Documentation provided by the member/patient's provider • Clinician reviewer's findings • Aetna's clinical criteria (e.g. CPB, MCG, LOCUS, CAOCUS) <p>While initial approval of services may be made by clinician reviewers, all denials must be decided by a physician, pharmacist, dentist, oral and maxillofacial surgeon, psychiatrist/psychologist/BCBA-D, depending on the type of services involved (see NCS 503-01). Both licensed staff clinicians (e.g., nurses) and physician reviewers have comparable experience in their respective specialties (see NCS 503-1). A denial is communicated in writing, along with options for appealing the denial and seeking peer-to-peer review. The process for review and the burdens of review for MH/SUD services is the same as for review of medical/surgical services.</p>	
Degree of Discretion	We apply the appropriate clinical criteria/guidelines and <u>clinical judgment</u> to the coverage determination. We allow discretion for making authorization decisions based on the professional scope of practice and clinical experience. See stringency controls above in support of the case that discretion does not arbitrarily disadvantage BH/SUD benefits.	
UM documentation requirements for MH/SUD and M/S	<p>Documentation requirements: NCS 503 – Medical Review:</p> <p>“F. Required Documentation:</p> <p>The applicable UM system documentation includes member demographics and information supporting clinical and benefit coverage determinations.</p>	

	<p>Staff includes the following documentation elements in the applicable UM system to support the coverage determination process:</p> <ul style="list-style-type: none">• The requested procedure/service/level of care.• The method of receipt (e.g., telephone, fax, e-mail, voice mail, on-site review), and the date of receipt;• The specific clinical criteria/guidelines (including number, edition and name) used in decision making (e.g., MCG 22nd edition, M-70 Cellulitis; CPB # 0050: Varicose Veins; LOCUS, V5, RTC);• A determination as to whether clinical criteria/guidelines are met; and,• The disposition of all material submitted as part of the coverage determination process (e.g., shredding of duplicate provider medical records when applicable after a coverage determination, backend imaging for unique documents). <p>Documentation for all coverage determinations (approvals and denials) requires all of the elements noted above as well as the following:</p> <ul style="list-style-type: none">• Date and time of the review (if different from the date and time of the system entry);• Name, title (if applicable) and the department/location (e.g., facility discharge planning department, PCP office) providing the information;• Relevant benefit limitations and the number of days, visits, services authorized through the current date, if applicable;• Pertinent clinical information to support coverage for the service or to substantiate the coverage denial determination;• Clinical criteria, guidelines, and/or other decision support tool(s) used in decision making including:• The specific criteria, guideline, standard met/not met;• Clear and specific documentation of the rationale used to make the coverage decision.• Coverage determination (e.g., approved, referred, or denied);• Notation of a same or similar specialty matched review (as appropriate) if conducted during the coverage determination process.
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Medical Necessity

Medical Necessity NQTL Analysis

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 Aetna or its designee, within Aetna'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. Aetna 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 Aetna's sole discretion.

Aetna 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 Aetna 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 (i.e., LOCUS/CALOCUS, ABA and ASAM), 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>

Services/ procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/ Surgical	MH/ SUD				
All inpatient, outpatient, and emergency care services		Medical necessity applies to all medical/surgical and mental health/substance use disorder benefits in each MHPAEA category and is based on generally accepted standards of care, as further detailed herein.	<p>The processes, strategies, and evidentiary standards include:</p> <p>MHPAEA provides that a plan may develop medical policies that limit care for mental health/substance use disorder benefits based on medical necessity as long as it does so for medical/surgical benefits and the “evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition”. 45 CFR 146.136(c)(4)(iii) (Example 4)</p> <ul style="list-style-type: none"> Evidence in the peer-reviewed published medical literature, Evidence-based consensus statements, expert opinions of healthcare providers Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies. Technology assessments and structured evidence reviews Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations such as: 	<p>Aetna’s strategy regarding satisfaction of parity’s NQTL requirements includes the utilization of an identical standard/definition of medical necessity.</p> <p>Medical and BH utilize appropriately applicable and generally accepted standards of practice to guide clinician with coverage determinations.</p> <p>For substance use disorder treatments, Aetna utilizes criteria developed by the American Society of Addiction Medicine (or ASAM) as a guideline to determine medical necessity. Every individual MH/SUD medical necessity determination is afforded independent clinical consideration based on the member’s presentation. This point is made clear to Aetna clinicians making medical necessity determinations in both the medical necessity tools utilized and in staff training. More information about LOCUS, CALOCUS/CASSII and ASAM criteria can be found on Aetna’s website at https://www.aetna.com/health-care-professionals/patient-care-programs/locat-aba-guidelines.html.</p> <p>For medical treatments Aetna utilizes Milliman Care Guidelines (MCG) as a guideline to determine the medical necessity.</p>	<p>As Written: 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 (see Appendix 2 for Council composition) and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines.</p> <p>In Operation: Aetna monitors the application of the medical necessity NQTL as follows:</p> <p>See In operations analysis for precertification as medical necessity is a component of the utilization review process.</p> <p>Further detail on the criteria:</p> <p>LOCUS/CALOCUS</p> <p>Aetna utilizes LOCUS and CALOCUS, which nationally is recognized (by several courts, regulators, and various external stakeholders) as a generally accepted standard of care tool, to guide clinicians in</p>

		<ul style="list-style-type: none">- Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Medicare Benefit Policy Manual- MCG guidelines- American Society of Addiction Medicine (ASAM) Criteria; Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, Third Edition- Applied Behavior Analysis Medical Necessity Guide- InterQual guidelines (as required by contractual provisions)- Level of Care Utilization System (LOCUS) for adults 18 years old and above and the Child and Adolescent Level of Care Utilization System/Child and Adolescent Service Intensity Instrument (CALOCUS/CASII)- <p>Review of generally accepted national quality standards, i.e.) National Committee for Quality Assurance, NQCA</p> <p>These processes, strategies, and evidentiary standards: are represented in Aetna Clinical Policies and in our published Aetna Clinical Policy Bulletins (CPBs) (https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html)</p> <p>In determining whether a medical technology is medically necessary and established, the</p>		<p>the making medically necessary level of care determinations for our Aetna members.</p> <p>The Level of Care Utilization System (LOCUS) assessment was developed to help determine the resource intensity needs of individuals who receive adult mental health services. The LOCUS was developed by the American Association of Community Psychiatrists (AACCP) in 1996. The LOCUS provides a system for assessment of needs based on 6 evaluation parameters:</p> <ul style="list-style-type: none">• Risk of harm• Functional status• Medical, addictive & psychiatric co-morbidity• Recovery Environment• Treatment and recovery history• Engagement and recovery status <p>The LOCUS assessment is reviewed and updated annually. There are multiple venues for regular input from all users as well as processes for continuous review and update of the tools themselves based on this input. Venues include:</p> <ul style="list-style-type: none">• National Council for Community Behavioral Healthcare/AACP LOCUS Advisory Committee• Deerfield Solutions
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		<p>Clinical Policy Council will consider whether the following five criteria are met:</p> <ul style="list-style-type: none">• Whether the medical technology has final approval from the appropriate governmental regulatory bodies• Whether the scientific evidence permits conclusions about the effect of the medical technology on health outcomes• Whether the medical technology improves net health outcomes• Whether the medical technology is at least as beneficial as any established alternatives• Whether the medical technology is more costly (taking into account all health expenses incurred in connection with the medical technology) than any equally effective established alternatives		<ul style="list-style-type: none">• AACP/AACAP Committee for CALOCUS/CASII <p>AACP Board of Directors Products and Service Plank</p> <p>CALOCUS/CASII</p> <p>The Child and Adolescent Level of Care Utilization System/Child and Adolescent Service Intensity Instrument (CALOCUS/CASII) assessment provides a framework for defining the appropriate character and intensity of both services and resources to meet the needs of children and adolescents . CALOCUS/CASII was developed by the American Association of Community Psychiatrists in collaboration with the American Association of Child and Adolescent Psychiatry and closely mirrors the structure of the LOCUS.</p> <p>The CALOCUS/CASI provides a system for assessment of needs based on 6 evaluation parameters:</p> <ul style="list-style-type: none">• Risk of harm• Functional status• Co-Occurrence of Conditions: medical, substance use, developmental and psychiatric• Environmental stress• Environmental support• Resilience and/or Response to Services
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				<div><div><ul style="list-style-type: none">○ Child and Adolescent Engagement in Service○ Parent/Primary Caregiver Engagement in Services</div><div><p>Similar to the LOCUS assessment, the CALOCUS/CASII assessment is reviewed and updated annually. There are multiple venues for regular input from all users as well as processes for continuous review and update of the tools themselves based on this input. Venues include:</p><ul style="list-style-type: none">• National Council for Community Behavioral Healthcare/AACP LOCUS Advisory Committee• Deerfield Solutions• AACP/AACAP Committee for CALOCUS/CASII• AACP Board of Directors Products and Services Plank</div><div><p>ASAM</p><p>For members seeking treatment for substance use disorders, Aetna utilizes the American Society of Addiction Medicine Criteria. The ASAM Criteria provides guidelines for evaluating the medical necessity of levels and types of care for substance use disorders. Many Courts and regulators consider ASAM a generally accepted, national standard for SUD treatment decisions. Some states, notably New York, New Jersey and Texas, require</p></div></div>
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				<p>state-specific SUD level of care criteria. In those states, we use the criteria required by law. ASAM revises its criteria from time to time in keeping with its established best practices. Such practices can be found at https://www.asam.org/resources/the-asam-criteria/about. Currently, Aetna is using the most recent version of the ASAM guidelines.</p> <p>MCG</p> <p>For medical/surgical health treatments, Aetna utilizes Milliman Care Guidelines, which nationally is a generally accepted standard of care tool, to guideline to clinicians in the making medically necessary level of care determinations for our Aetna members.</p> <p>Clinical Policy Bulletins (CPBs)</p> <p>The Aetna Clinical Policy Council evaluates the safety, effectiveness and appropriateness of medical technologies (e.g., drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided) that are covered under Aetna medical plans, or that may be eligible for coverage under Aetna medical plans. In making this determination, the Clinical Policy Council will review and evaluate evidence in the peer-reviewed published medical literature, information from the U.S. Food and Drug Administration and other Federal public health agencies, evidence-based guidelines from national medical professional organizations, and evidence-based</p>
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				<p>evaluations by consensus panels and technology evaluation bodies.</p> <p>The Clinical Policy council is comprised of pharmacists and medical directors from the Medical Policy Administration (MPA) department, National Accounts department, Behavioral Health department, Clinical Pharmacy department and regional Patient Management units. The Clinical Policy council usually convenes twice monthly.</p> <ul style="list-style-type: none">• Both new and revised CPB drafts undergo a comprehensive review process. This includes review by our Clinical Policy Council and external practicing clinicians, and approval by our chief medical officer or their designee.• Drafts of new and revised CPBs are distributed for review to members of the Clinical Policy Council prior to each meeting. Each new and revised draft CPB is placed on the Clinical Policy Council agenda and is discussed during the meeting. The Clinical Policy Council votes whether or not to recommend approval of each draft CPB. In addition, the Clinical Policy Council may recommend other revisions to a draft CPB.• The CPB draft may be revised based on the Clinical Policy Council's recommendations. CPB drafts are reviewed by our Legal department and the head of the Medical Policy Administration department, and further revisions to draft CPBs may be made based on their recommendations. Draft CPBs are sent to the chief medical officer
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				<p>or their designee for review and final approval. Draft CPBs that are approved by the chief medical officer or their designee will be published on our websites within 60 days of the Clinical Policy council's recommendations.</p> <ul style="list-style-type: none">• CPBs are reviewed annually unless relevant new medical literature, guidelines, regulatory actions, or other relevant new information warrants more frequent review. Each time a CPB is updated, a comprehensive search of the peer-reviewed published medical literature is performed to determine if there is a change in the experimental and investigational status or medical necessity of medical technologies addressed in each CPB. If the Clinical Policy unit determines that new evidence or other information has emerged to warrant consideration of a change in our clinical policy, a revised CPB is prepared. If no new evidence has emerged that would warrant a change in position, the CPB may be updated with additional supporting background information and references. Each revised and updated CPB is submitted to the Clinical Policy Council for review and approval.• In developing our CPBs, for each medical technology selected for evaluation, the Clinical Policy unit conducts a comprehensive search of the peer-reviewed published medical literature indexed in the National Library of Medicine PubMed Database, assesses the regulatory status of the technology,
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				<p>reviews relevant evidence-based clinical practice guidelines and related documents indexed in the Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse Database, and reviews relevant technology assessments indexed in the National Library of Medicine’s Health Services/Technology Assessment Text (HSTAT) Database. Also, the opinions of relevant experts may be obtained where necessary.</p> <ul style="list-style-type: none">• Each CPB includes a policy statement and references to the medical literature and other sources used in developing the clinical policy. In addition, the CPB may include a background section that describes the medical technology and provides the rationale for our policy.• In addition, each CPB has a coding section that provides applicable International Classification of Diseases (ICD), Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes.
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Sequenced Treatment

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

Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/SUD				
See List below	Transcranial Magnetic Stimulation Gender reassignment	Note: <u>all factors are the same for medical/surgical and MH/SUD</u> <ul style="list-style-type: none"> Treatment efficacy based on evidence-based criteria (EBC). Evidenced based medicine is an approach to medical practice intended to optimize decision making by emphasizing the use of evidence from well- designed and well conducted research. There must be at least one EBC tool available to assist clinicians with determinations related to sequenced treatment use. EBC may be sourced from (as noted above) national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies or criteria from professional associations. 	Evidence based guidelines and or criteria exist for all medical/surgical and MH/SUD uses of sequenced treatment. <ul style="list-style-type: none"> Availability of EBC exist for all of these services via Aetna Clinical Policy Bulletins (CPBs) CPB numbers for the one BH/SUD sequenced treatment noted and for all of the Medical Surgical sequenced treatments listed are noted and are available publicly at: aetna.com/health-care-professionals/clinical-policy-bulletins.html and are noted below Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations including: the NIMH sequenced treatment alternatives to relieve Depression (STAR*D Study), and an American Psychiatric Association (APA) practice guideline on major depression (2010, reaffirmed 2015). 	Confirmation of evidence-based guidelines and criteria found in the specified CPBs for all Medical Surgical and MH/SUD procedures, services, devices and therapies including sequenced treatment and review of those guidelines demonstrates that a consistent methodology, which is aligned to generally accepted practice standards, was applied to the development of this NQTL. The MH/SUD benefits for which sequenced treatment requirements apply are no more stringent than those applied to medical surgical benefits	<p>As Written: The Clinical Policy Bulletin (CPB) evidence-based guidelines used in the sequenced treatment requirements for medical surgical back pain invasive procedures, spinal surgery, total hip replacement, obesity surgery, Vagus Nerve Stimulation, Spinal Cord Stimulation, Deep Brain Stimulation, Urinary incontinence procedures as well as those used for gender reassignment and TMS undergo a comprehensive review process and have been found to be aligned to generally accepted practice standards. This validation is completed by our Clinical Policy Council and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines.</p> <p>In Operation: Audits demonstrating application of these sequenced treatment requirements.</p>

Services Subject to Sequenced Treatment Requirement

Service	Clinical Policy Bulletin #
TMS	0469 https://www.aetna.com/cpb/medical/data/400_499/0469.html
Gender reassignment	0615 http://www.aetna.com/cpb/medical/data/600_699/0615.html
Back Pain Invasive Procedures	0016 aetna.com/cpb/medical/data/1_99/0016.html
Spinal Surgery	0743 aetna.com/cpb/medical/data/700_799/0743.html
Total Hip Replacement	0287 aetna.com/cpb/medical/data/200_299/0287.html
Obesity Surgery	157 http://aetnet.aetna.com/mpa/cpb/100_199/0157.html
Vagus Nerve Stimulation	191 http://aetnet.aetna.com/mpa/cpb/100_199/0191.html
Spinal Cord Stimulation	194 http://aetnet.aetna.com/mpa/cpb/100_199/0194.html
Deep Brain Stimulation	208 http://aetnet.aetna.com/mpa/cpb/200_299/0208.html
Urinary incontinence	223 http://aetnet.aetna.com/mpa/cpb/200_299/0223.html
Sleep latency testing	512 http://www.aetna.com/cpb/medical/data/300_399/0330.html
Obstructive Sleep Apnea	752 http://www.aetna.com/cpb/medical/data/700_799/0752.html
Feeding programs	809 http://www.aetna.com/cpb/medical/data/800_899/0809.html

Treatment Plan Requirement

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

Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/ Surgical	MH/SUD				
Cardiac Rehabilitation Hyperbaric Oxygen Therapy Proton Beam Therapy Physical Therapy Occupational Therapy Speech Therapy	Applied Behavior Analysis for a diagnosis of Autism Spectrum Disorder	<p>Note: all factors are the same for medical/surgical and MH/SUD</p> <ul style="list-style-type: none">Treatment efficacy based on evidence-based criteria (EBC). Evidenced based medicine is an approach to medical practice intended to optimize decision making by emphasizing the use of evidence from well- designed and well conducted research.There must be at least one EBC tool available to assist clinicians with determinations related to sequenced treatment use. EBC may be sourced from (as noted above) national medical professional organizations, evidence-based evaluations by consensus panels and technology evaluation bodies or criteria from professional associations.	<p>Evidence based guidelines and or criteria exist for all medical/surgical and MH/SUD uses of treatment plans to establish medical necessity.</p> <ul style="list-style-type: none">Availability of EBC exist for all of these services via Aetna Clinical Policy Bulletins (CPBs) CPB numbers for the one BH/SUD treatment plan required service noted and for all of the Medical Surgical treatment plan required services are noted and are available publicly at : aetna.com/health-care-professionals/clinical-policy-bulletins.html and are noted belowReview of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations including: -Behavior Analyst Certification Board’s Applied Behavior Analysis Treatment of Autism Spectrum Disorder: Practice Guidelines for Healthcare Funders and Managers	<p>Confirmation of evidence-based guidelines and criteria found in the specified CPBs for all Medical Surgical and MH/SUD procedures, services, devices and therapies including treatment plan requirement and review of those guidelines demonstrates that a consistent methodology, which is aligned to generally accepted practice standards, was applied to the development of this NQTL. The MH/SUD benefits for which treatment plan requirements apply are no more stringent than those applied to medical surgical benefits.</p>	<p>As Written: The CPBs used in the Treatment Plan requirements that relates to Cardiac Rehabilitation, Proton Beam, Physical Therapy, Occupational Therapy, Speech Therapy, Hyperbaric oxygen therapy, and Applied Behavior Analysis review process have been found to be aligned to generally accepted practice standards. This validation is completed by our Clinical Policy Council and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines.</p> <p>In Operation: Audits demonstrating application of these treatment plan requirements available upon request.</p>

Services Subject to Treatment Plan Requirement

Service	Clinical Policy Bulletin #
ABA	0554 http://aetnet.aetna.com/mpa/cpb/500_599/0554.html
Cardiac Rehabilitation: Outpatient	0021 http://aetnet.aetna.com/mpa/cpb/1_99/0021.html
Physical Therapy	0325 http://aetnet.aetna.com/mpa/cpb/300_399/0325.html
Occupational Therapy	0250 http://aetnet.aetna.com/mpa/cpb/200_299/0250.html
Speech Therapy	0243 http://aetnet.aetna.com/mpa/cpb/200_299/0243.html
Hyperbaric oxygen therapy	0172 https://www.aetna.com/cpb/medical/data/100_199/0172.html
Proton Beam	0270 https://www.aetna.com/cpb/medical/data/200_299/0270.html

Benefit Exclusion

Experimental or Investigational Services or Unproven Services NQTL Analysis

Medical, surgical, diagnostic, psychiatric, substance abuse or health care services, technologies, supplies, treatments, procedures, drug therapies or devices that, at the time Aetna makes a determination regarding coverage in a particular case, are determined to be any of the following:

- Not approved by the US Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopeia Dispensing Information as appropriate for the proposed use
- Subject to review and approval by any institutional review board for the proposed use
- The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight.

Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/ SUD				
All inpatient, outpatient, and emergency care services		<p>Factors used in the development of the experimental/investigational NQTL are listed below.</p> <p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <p>Lack of appropriate evidence establishing the safety and effectiveness of the service.</p>	<p>The processes, strategies, and evidentiary standards used to define the factors include the following:</p> <ul style="list-style-type: none"> • There are insufficient outcomes data available from controlled clinical trials published in the peer-reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or • Approval required by the FDA has not been granted for marketing; or • A recognized national medical or dental society or regulatory agency has determined, in writing, that it is experimental or investigational, or for research purposes; or • It is a type of drug, device or treatment that is the subject of a Phase I or Phase II clinical trial or the experimental or research arm of a Phase III clinical trial, using the definition of “phases” indicated in regulations and other official actions and publications of the FDA and Department of Health and Human Services; or • The written protocol or protocols used by the treating facility, or the protocol or protocols of any other facility, informed consent form used by the treating facility or 	<p>The Aetna Clinical Policy Council ongoing evaluation of Aetna’s CPBs reveals a consistent methodology of determining the experimental/investigational status of various services.</p>	<p>As Written: The CPBs used for various Benefit Exclusion requirements have been found to be aligned to generally accepted practice standards. This validation is completed by our Clinical Policy Council and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines.</p> <p>In Operation: Aetna monitors the application of the medical necessity NQTL as follows:</p> <p>The Clinical Policy Bulletins (CPBs) evidenced-based criteria which is used in administering various benefit exclusions.</p> <p>Exclusions, as detailed in our CPBs, undergo a comprehensive review process. This includes review by our Clinical Policy Council and external practicing clinicians, and approval by our chief medical officer or their designee. This process involves annual review of generally accepted national evidence-based guidelines as further detailed in the Medical Necessity NQTL analysis above.</p> <p>In making this determination, the Clinical Policy Council will review and evaluate evidence in the peer-reviewed published medical literature, information from the U.S. Food and Drug Administration and other Federal public health agencies, evidence-based guidelines from national medical professional</p>

Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/ SUD				
			<p>by another facility studying the same drug, device, procedure, or treatment states that it is experimental or investigational, or for research purposes.</p> <ul style="list-style-type: none">Review of generally accepted national evidence-based guidelines from national medical professional organizations, evidence-based evaluations by consensus panels, and technology evaluation bodies or criteria from professional associations such as:<ul style="list-style-type: none">Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs) and Medicare Benefit Policy Manual<ul style="list-style-type: none">MCG guidelinesAmerican Society of Addiction Medicine (ASAM) Criteria; Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, Third EditionApplied Behavior Analysis Medical Necessity GuideInterQual guidelines (as required by contractual provisions) <p>Review of generally accepted national quality standards, e.g. National Committee for Quality Assurance, NCQA</p>		<p>organizations, and evidence-based evaluations by consensus panels and technology evaluation bodies.</p> <p>The Clinical Policy council is comprised of pharmacists and medical directors from the Medical Policy Administration (MPA) department, National Accounts department, Behavioral Health department, Clinical Pharmacy department and regional Patient Management units. The Clinical Policy council usually convenes twice monthly.</p> <p>Discretion: Exclusion of experimental/investigational benefits will not apply with respect to services or supplies (other than drugs) received in connection with a disease; if Aetna determines that:</p> <ul style="list-style-type: none">The disease can be expected to cause death within one year, in the absence of effective treatment; andThe care or treatment is effective for that disease or shows promise of being effective for that disease as demonstrated by scientific data. In making this determination, Aetna will take into account the results of a review by a panel of independent medical professionals. They will be selected by Aetna. This panel will include professionals who treat the type of disease involved.Also, this exclusion will not apply with respect to drugs that: have been granted treatment investigational new drug (IND)

Services/procedures to which the NQTL applies		Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, strategies, evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Medical/Surgical	MH/ SUD				
			<p>These processes, strategies, and evidentiary standards: are represented in Aetna Clinical Policies and in our published Aetna Clinical Policy Bulletins (CPBs) https://www.aetna.com/health-care-professionals/clinical-policy-bulletins.html</p> <p>In determining whether a medical technology is medically necessary and established, the Clinical Policy Council will consider whether the following five criteria are met:</p> <ul style="list-style-type: none">• Whether the medical technology has final approval from the appropriate governmental regulatory bodies• Whether the scientific evidence permits conclusions about the effect of the medical technology on health outcomes• Whether the medical technology improves net health outcomes• Whether the medical technology is at least as beneficial as any established alternatives• Whether the medical technology is more costly (taking into account all health expenses incurred in connection with the medical technology) than any equally effective established alternatives		<p>or Group C treatment IND status; or are being studied at the Phase III level in a national clinical trial sponsored by the National Cancer Institute; if Aetna determines that available scientific evidence demonstrates that the drug is effective or shows promise of being effective for the disease.</p> <ul style="list-style-type: none">• With regard to Aetna’s Medical Technology Evaluation and Clinical Policy Development Process, Aetna’s Clinical Policy Bulletins (CPBs) previously referenced define our policy regarding the experimental and investigational status and medical necessity of medical technologies (e.g., medical and surgical procedures, devices, pharmaceuticals, biological products, behavioral health interventions, and the organizational and supportive systems within which such care is provided) that may be eligible for coverage under our medical plans. The CPBs are used in conjunction with the terms of the member’s benefit plan and other Aetna-recognized criteria to determine health care coverage for our members.

Network NQTLs

The following framework organizes the factors, sources, methods, analysis and stringency application applied to the inpatient and outpatient benefit classifications for NQTLs in the following categories: participating provider reimbursement, non-participating provider reimbursement, participating facility reimbursement, non-participating facility reimbursement, network adequacy, provider admission standards for outpatient, group and individual plans and provider admission standards for facility and facility-based practitioners.

Participating Provider Reimbursement NQTL

Negotiated charge 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).

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered in-network	Applies to all M/S benefits delivered in-network	<p>Note: All factors are the same for medical/surgical and MH/SUD</p> <ul style="list-style-type: none"> Reimbursement rate indices (e.g. Medicare reimbursement rates) Market dynamics (e.g. supply and demand) Provider type (e.g. MD, NP) Service type (e.g. counseling, initial assessment) Performance based programs 	<ul style="list-style-type: none"> Standard fee schedules: <ul style="list-style-type: none"> Benchmarked from Medicare reimbursement rates Developed for each market based on market analysis Final negotiated rate – either standard rates or a negotiated fee schedule 	<p>MH/SUD standard fee schedule rates can be higher but are not lower than medical rates for the same codes that can be used by BH and medical/surgical providers. The process to determine provider network reimbursement between Medical/Surgical and MH/SUD is as follows:</p> <p>Medical informs Behavioral Health that they are adjusting the standard rates for a given market. Medical supplies the new medical rates for the codes shared with the behavioral health fee schedule.</p> <p>BH will provide rates to medical for MH/SUD services in the BH Network. Behavioral Health will compare the rates to the medical rates. If the medical rate is the higher rate, Behavioral Health will adopt the medical rate. Behavioral Health will cascade the rate down to the lower level providers using the following CMS guidelines and commensurate with level of training :</p> <ul style="list-style-type: none"> MD's (MH/SUD and medical/surgical) & Clinical Psychologists receive 100% of the rate Nurse Practitioners, Physician Assistants and Certified Nurse Specialist (MH/SUD and 	<p>As Written: Aetna maintains uniform reimbursement practices that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application of this NQTL through several initiatives:</p> <ul style="list-style-type: none"> Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care. Rates are updated, and new schedules are completed and reviewed by a different person to make sure they are accurate. The rates are reviewed on both Medical and BH by members

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
				<p>medical/surgical) receives 85% of the new rate**</p> <ul style="list-style-type: none">• Drug and Alcohol Counselor, Licensed Professional Counselor, Marriage and Family Therapist, Pastoral Counselor, Social Worker receives 75% of the new rate***• Audiologist, Registered Dietician, Genetic Counselor, Massage Therapist, Nutritionist, Respiratory Therapist receives 75% of the new rate <p>** If the existing MH/SUD rate is higher than 85% of the new rate, the already existing rate stays in place *** If the existing MH/SUD rate is higher than the 75% of the new rate, the already existing rate stays in place</p> <p>The rates are effective at the same time as the new medical rates.</p> <p>MH/SUD rates can be updated in addition to the rate updates triggered by the Medical rate updates.</p>	<p>of the enterprise senior network team as well as by members of the senior regional market team.</p>

Non-Participating Provider Reimbursement NQTL

Allowable amount is the amount of an out-of-network provider's charge that is eligible for coverage. The allowable amount depends on the geographic area where members get the service or supply.

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered out-of-network	Applies to all M/S benefits delivered out-of-network	<p>Note: All factors are the same for medical/surgical and MH/SUD</p> <ul style="list-style-type: none"> Reasonable and Customary rates benchmarked from reimbursement rate indices The Centers for Medicare and Medicaid Services' (CMS) National Correct Coding Initiative (NCCI) and other external materials that say what billing and coding practices are and are not appropriate Generally accepted standards of medical and dental practice The views of physicians and dentists practicing in the relevant clinical areas Aetna's own data and/or databases and methodologies maintained by third parties. 	<ul style="list-style-type: none"> Rate hierarchy (i.e. a preset algorithm that generates the rate that will be paid based on certain factors) Market analysis when rate hierarchy is not applicable Final rate negotiated as part of the rate hierarchy process Vendor contracts Third-party claim and code review 	<p>Aetna compensates nonparticipating providers based on member's plan and benefit level subject to the lesser of either the billed charges or the allowable amount determined by a standard rate hierarchy that is the same for both MH/SUD and M/S.</p> <p>For Aetna's standard fully insured plans, Aetna's claim payment system follows these steps in attempting to price non-participating claims.</p> <p>If one step is unsuccessful, we move on to the next until the claim is successfully priced. These steps may vary by type of non-participating claim.</p> <p>First tier of hierarchy includes Single-case contracting (pre-service negotiations), second tier includes availability of a National Advantage Program (NAP) rate, third tier includes the Plan rate, fourth tier includes facility charge review, fifth tier includes ad hoc NAP post-service negotiations, and sixth tier involves non-par reasonable/default rate.</p> <p>Where reimbursement is based on Aetna's OON schedules then:</p> <ul style="list-style-type: none"> MD's (MH/SUD and medical/surgical) & Clinical Psychologists receive 100% of the rate All other provider types receives 85% of the new rate 	<p>As Written: Aetna maintains uniform reimbursement practices that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application of this NQTL through:</p> <ul style="list-style-type: none"> Mental Health (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.

Participating Facility Reimbursement NQTL

Negotiated charge 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).

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered in-network	Applies to all M/S benefits delivered in-network	<p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <ul style="list-style-type: none">market dynamics (e.g. supply and demand, volume with Aetna)Performance based programsScope and complexity of services providedAetna membership presence within region	<ul style="list-style-type: none">Benchmarked from Medicare Inpatient Psychiatric Facility Prospective Payment SystemMarket analysisNegotiated reimbursement models (e.g. per diem versus DRG)Final rate negotiated from standard target ranges	<p>Prior to negotiating such rates with a particular facility provider, Aetna has developed a set of standard target rates based on the average rates paid for similar services in a particular market. These target rates are updated annually based on average rate increases.</p> <p>Rates are then negotiated on the basis of these target ranges, rather than a set fee schedule. In general, the majority of rates negotiated with freestanding facilities fall within a targeted rate range differential to the average as a whole.</p>	<p>As Written: Aetna maintains uniform reimbursement practices that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application of this NQTL through:</p> <ul style="list-style-type: none">Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.

Non-Participating Facility Reimbursement NQTL

Allowable amount is the amount of an out-of-network provider’s charge that is eligible for coverage. The allowable amount depends on the geographic area where members get the service or supply.

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered out of network	Applies to all M/S benefits delivered out of network	<p>Note: All factors are the same for medical/surgical and MH/SUD</p> <ul style="list-style-type: none">Reasonable and Customary rates benchmarked from reimbursement rate indices	<ul style="list-style-type: none">Rate hierarchy (i.e. a preset algorithm that generates the rate that will be paid based on certain factors)Market analysis when rate hierarchy is not applicableFinal rate negotiated as part of the rate hierarchy process	<p>Aetna compensates nonparticipating providers based on member’s plan and benefit level subject to the lesser of either the billed charges or the allowable amount determined by a standard rate hierarchy that is the same for both MH/SUD and M/S.</p> <p>For Aetna’s standard fully insured plans, Aetna’s claim payment system follows these steps in attempting to price non-participating claims.</p> <p>If one step is unsuccessful, we move on to the next until the claim is successfully priced. These steps may vary by type of non-participating claim.</p> <p>First tier of hierarchy includes Single-case contracting (pre-service negotiations), second tier includes availability of a National Advantage Program (NAP) rate, third tier includes the Plan rate, fourth tier includes facility charge review, fifth tier includes ad hoc NAP post-service negotiations, and sixth tier involves non-par reasonable/default rate</p> <p>Where reimbursement is based on Aetna’s OON schedules then:</p> <ul style="list-style-type: none">MD’s (MH/SUD and medical/surgical) & Clinical Psychologists receive 100% of the rateAll other provider types receives 85% of the new rate	<p>As Written: Aetna maintains uniform reimbursement practices that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application of this NQTL through several initiatives:</p> <ul style="list-style-type: none">Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets bi- weekly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care

Network Adequacy NQTL

Aetna maintains sufficient numbers and types of primary care, behavioral health and specialty care practitioners in its network. Aetna maintains an adequate network of primary care, behavioral healthcare and specialty care practitioners (SCP) and monitors how effectively this network meets the needs and preferences of its membership. Aetna establishes mechanisms to provide access to appointments for primary care services, behavioral healthcare services and specialty care services. Aetna provides and maintains appropriate access to primary care services, behavioral healthcare services and specialty care services.

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered in-network	Applies to all M/S benefits delivered in-network	<p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <ul style="list-style-type: none">Applicable state law, federal law, and accreditation network adequacy requirements	<ul style="list-style-type: none">Aetna’s standards approved by NCQA in accrediting Aetna. Aetna has NCQA accreditation as a Health Plan and a Managed Behavioral Healthcare Organization (“Aetna’s NCQA Standards”)Network adequacy indicators are based on NCQAs NET 1 (AVAILABILITY OF PRACTITIONERS) and NET 2 (ACCESSIBILITY OF SERVICES)State specific Network Adequacy as applicable	The same standards are used to define and monitor minimum requirements for network composition, ensure compliance with applicable state and federal regulatory standards, and to ensure compliance with applicable accreditations standards for both M/S and MH/SUD.	<p>As Written: Aetna maintains uniform network adequacy practices that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In operation: Aetna monitors the application of this NQTL through several initiatives:</p> <ul style="list-style-type: none">Oversight of network adequacy reporting by the National Quality Oversight Committee NQOC.<ul style="list-style-type: none">A qualitative and quantitative analysis by product/product line is performed using network adequacy data which includes member complaints/grievances and appeals, accessibility, availability, out of network requests, and member experience data (CAHPS or member experience survey).Network adequacy complaints/grievances and appeals at or in excess of .01 per thousand member months will trigger an additional review. The rate per thousand member months shall be calculated as follows: [# of complaints or appeals]/(monthly total for 12 months of membership/1000)]Out-Of-Network requests for and utilization services will be reported at the product line-level per thousand members. The rate per thousand members shall be calculated as follows: [# of Out-of-Network requests)/1,000 enrollees] (membership/1000).

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
					The results of the above analysis will be reviewed in conjunction with the findings of the network availability and accessibility analyses to identify and prioritize opportunities for improvement. One improvement for non-behavioral health and one for behavioral health will be implemented.

Provider Admission Standards NQTL: Outpatient group and individual providers

Credentialing is a process by which a health care organization reviews and evaluates qualifications of licensed independent practitioners to provide services to its members/enrollees. Eligibility is determined by the extent to which applicants meet defined requirements for education, licensure, professional standing, service availability and accessibility, as well as for conformity to the organization’s utilization and quality management requirements.

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered in-network	Applies to all M/S benefits delivered in-network	<p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <ul style="list-style-type: none">Applicable state law, federal law, and accreditation practice requirements	<ul style="list-style-type: none">Aetna’s NCQA StandardsVerification 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.	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	<p>As Written Aetna maintains one set of credentialing policies that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application this NQTL through several initiatives:</p> <ul style="list-style-type: none">Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.Credentialing rate and turnaround time reports (refer to Appendix 8)

Provider Admission Standards NQTL: Facility and Facility-Based Practitioners

Credentialing is a process by which a health care organization reviews and evaluates qualifications of licensed independent practitioners to provide services to its members/enrollees. Eligibility is determined by the extent to which applicants meet defined requirements for education, licensure, professional standing, service availability and accessibility, as well as for conformity to the organization’s utilization and quality management requirements.

NQTL applies to MH/SUD	NQTL applies to M/S	Factors: <i>Factors used in the development of the limitation</i>	Sources: <i>Processes, Strategies, and evidentiary standards</i>	Comparability Analysis: <i>Results of the comparison of MH/SUD and Medical/Surgical</i>	Stringency: <i>Evidence to establish that the limitation is applied no more stringently, as written and in operation, to MH/SUD benefits than to M/S benefits</i>
Applies to all MH/SUD benefits delivered in-network	Applies to all M/S benefits delivered in-network	<p>Note: <u>All factors are the same for medical/surgical and MH/SUD</u></p> <ul style="list-style-type: none">Applicable state law, federal law, and accreditation practice requirements	<ul style="list-style-type: none">Aetna’s NCQA StandardsFacility qualifications are reviewed to ensure facility meets Aetna’s established requirements for organizational credentialing, including state licensing board, operating/certificate of occupancy, accreditation entity.	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.	<p>As Written: Aetna maintains one set of credentialing policies that are equally applicable to MH/SUD and medical/surgical. See Appendix 1 for a listing of core policies.</p> <p>In Operation: Aetna monitors the application this NQTL through several initiatives:</p> <ul style="list-style-type: none">Mental Health Parity (MHP) Task Force: Multi-disciplinary team that meets monthly to establish parity compliance protocols; clarify interpretation of parity regulations, FAQs, and related requirements; and to respond to internal and external parity questions and requests. Subgroups comprised of both Behavioral Health and Medical Surgical Clinical and other administrative personnel meet more frequently and as needed to ensure compliance in specific policy and operational areas, i.e.) network management, clinical management by level of care.Credentialing rate and turnaround time reports (refer to Appendix 9)

Appendix 1

Relevant Core Policies

NCS 100-01 Precertification Policy
NCS 200-01 Concurrent Review Policy
NCS-300-01 Retrospective Review Policy
NCS 503-01 Medical Review Policy
NCS 504-01 Timeliness Standards for Coverage Decisions and Notification Policy
NCS 505-01 Denial of Coverage Policy and Notification
NCS 506-01 Peer-to-Peer Review Policy
NCS 510-01 Internal Quality Review Policy
QM 7 Member Access to Practitioners and Member Services
QM 10 Provider Availability Standards
QM 51 Assessment of Organizational Providers
QM 53 Credentialing Allied Health Practitioners
QM 54 Practitioner Credentialing/Recredentialing Policy

Appendix 2

Clinical Policy Council Composition

Role	Credentials	Job Title	Organization	Board Certified Specialty (if applicable)
Representing Chief Medical Officer (CMO)	MD	VP, Aetna Quality Management and Clinical Policy Development	Aetna Medical Affairs	Family Medicine
Council Chairman (only votes in case of a tie)	MD	Medical Director	Medical Policy & Operations (MPO)	Anesthesiology
Head of clinical policy research & development	MD	Senior Director of Clinical Policy Research & Development	Aetna Medical Affairs, Clinical Policy Unit	General Practice
Council Secretary; Clinical policy research & development support	APRN, NP-C, PCCN-K	Health Service Manager	Aetna Medical Affairs, Clinical Policy Unit	Adult-Gerontology
Council Secretary (alternate); Clinical policy research & development support	PharmD	Health Service Manager	Aetna Medical Affairs, Clinical Policy Unit	Pharmacy
Council Secretary (alternate); Clinical policy	PhD	Lead Business Consultant	Aetna Medical Affairs, Clinical Policy Unit	

research and development support				
Representing Medical Policy & Operations (MPO)/Coding	MD, FAAP	Senior Director, Clinical Solutions	Medical Policy & Operations (MPO)	Pediatrics
Representing National Medical Excellence Program (NME)	MD, MBA	Senior Director, Clinical Solutions	Medical Policy & Operations (MPO), Special Case Precert Unit	Obstetrics & Gynecology
Representing National Accounts	MD	Senior Medical Director	National Accounts (NACMST)	Family Medicine
	MD	Medical Director		Occupational Medicine/Internal Medicine/Public Health & General Preventative
Representing Pharmacy	RPh	Director, Clinical Pharmacy	Aetna Pharmacy	Pharmacy
Representing Pharmacy	RN	Senior Director, Business Consultation	Aetna Pharmacy	
Representing West Territory	MD	Medical Director	Clinical Health Services – CA MD	Anatomic and Clinical Pathology
Representing North Central Territory	MD	Medical Director	Clinical Health Services – OH/KY MDs	Emergency Medicine
Representing South Central Territory	MD	Medical Director	MDA South Central MDs	Internal Medicine

Representing North Atlantic Territory	MD, MBA, FACS DO, FAAFP	Medical Director Senior Medical Director, Clinical Solutions MD	Clinical Health Services - NJ MD Clinical Solutions CM MDs	General Surgeon Family Medicine
Representing North Atlantic Territory	MD, FCCP MD	Medical Director Medical Director & Team Lead	Clinical Health Services – MD/DC/VA MDs Clinical Health Services – PA/DE/WV MDs East; Keystone Market	Pulmonary Medicine/Internal Medicine Family Medicine
Representing Southeast Territory	MD, MHA	Senior Director, Clinical Solutions	Clinical Health Services Southwest MD	Internal Medicine/Pediatrics
Representing Compliance	MD	Senior Medical Director	Compliance	Internal Medicine
Representing Medicare	MD	Senior Director, Medical Health Service	Medicare Medical Operations	Internal Medicine
Representing Medicaid	DO	Deputy CMO	National Medical Management, Aetna Medicaid	Emergency Medicine
Representing Behavioral Health	MMM, MD, CPE, DFAPA	Senior Medical Director	Behavioral Health	Psychiatry
Representing Active Health	MD, MSc, CPE	Senior Director, Medical Health Service	Active Health Research and Development	Family Medicine
Representing Aetna Student Health	MD	Senior Medical Director	Clinical Solutions Transformation	Family Medicine
Representing Aetna International	MD	Senior Director, Clinical Solutions	Clinical Health Services CMO	Internal Medicine

Role	Credentials	Job Title	Organization	Board Certified Specialty (if applicable)
Representing Chief Medical Officer (CMO)	MD	VP, Aetna Quality Management and Clinical Policy Development	Aetna Medical Affairs	Family Medicine
Council Chairman (only votes in case of a tie)	MD	Medical Director	Medical Policy & Operations (MPO)	Anesthesiology
Head of clinical policy research & development	MD	Senior Director of Clinical Policy Research & Development	Aetna Medical Affairs, Clinical Policy Unit	General Practice
Council Secretary; Clinical policy research & development support	APRN, NP-C, PCCN-K	Health Service Manager	Aetna Medical Affairs, Clinical Policy Unit	Adult-Gerontology
Council Secretary (alternate); Clinical policy research & development support	PharmD	Health Service Manager	Aetna Medical Affairs, Clinical Policy Unit	Pharmacy
Council Secretary (alternate); Clinical policy research and development support	PhD	Lead Business Consultant	Aetna Medical Affairs, Clinical Policy Unit	

Representing Medical Policy & Operations (MPO)/Coding	MD, FAAP	Senior Director, Clinical Solutions	Medical Policy & Operations (MPO)	Pediatrics
Representing National Medical Excellence Program (NME)	MD, MBA	Senior Director, Clinical Solutions	Medical Policy & Operations (MPO), Special Case Precert Unit	Obstetrics & Gynecology
Representing National Accounts	MD	Senior Medical Director	National Accounts (NACMST)	Family Medicine
	MD	Medical Director		Occupational Medicine/Internal Medicine/Public Health & General Preventative
Representing Pharmacy	RPh	Director, Clinical Pharmacy	Aetna Pharmacy	Pharmacy
Representing Pharmacy	RN	Senior Director, Business Consultation	Aetna Pharmacy	
Representing West Territory	MD	Medical Director	Clinical Health Services – CA MD	Anatomic and Clinical Pathology
Representing North Central Territory	MD	Medical Director	Clinical Health Services – OH/KY MDs	Emergency Medicine
Representing South Central Territory	MD	Medical Director	MDA South Central MDs	Internal Medicine
	MD, MBA, FACS	Medical Director	Clinical Health Services - NJ MD	General Surgeon

Representing North Atlantic Territory	DO, FAAFP	Senior Medical Director, Clinical Solutions MD	Clinical Solutions CM MDs	Family Medicine
Representing North Atlantic Territory	MD, FCCP	Medical Director	Clinical Health Services – MD/DC/VA MDs	Pulmonary Medicine/Internal Medicine
	MD	Medical Director & Team Lead	Clinical Health Services – PA/DE/WV MDs East; Keystone Market	Family Medicine
Representing Southeast Territory	MD, MHA	Senior Director, Clinical Solutions	Clinical Health Services Southwest MD	Internal Medicine/Pediatrics
Representing Compliance	MD	Senior Medical Director	Compliance	Internal Medicine
Representing Medicare	MD	Senior Director, Medical Health Service	Medicare Medical Operations	Internal Medicine
Representing Medicaid	DO	Deputy CMO	National Medical Management, Aetna Medicaid	Emergency Medicine
Representing Behavioral Health	MMM, MD, CPE, DFAPA	Senior Medical Director	Behavioral Health	Psychiatry
Representing Active Health	MD, MSc, CPE	Senior Director, Medical Health Service	Active Health Research and Development	Family Medicine
Representing Aetna Student Health	MD	Senior Medical Director	Clinical Solutions Transformation	Family Medicine
Representing Aetna International	MD	Senior Director, Clinical Solutions	Clinical Health Services CMO	Internal Medicine

Appendix 3

NPL Committee Composition

Role	Credentials	Job Title	Organization	Board Certified Specialty
Chair	DO	VP, Clinical Strategic Operations and Policy delivery	Consumer Health and Services, Innovation Solutions	Internal Medicine
member	MD, MHA, FACPE, FAAFP	Sr Dir, Clinical Solutions MD	Territories	Family Medicine
member	MD, MBA	Senior Medical Director	National Accounts Care Management Solutions Team	Internal Medicine
member	MD	Exec Dir, NMD, Medicare	Medicare	Internal Medicine
member	MD	Medical Director	Territories	Pediatrics
member	MD, DFAPA	Senior Director, Medical Health Service	Territories	Psychiatry
member	MD, MBA	Sr. Dir. Clinical Solutions MD	Territories	Obstetrics & Gynecology
member	MD	Senior Medical Director	Consumer Health and Services, Innovation Solutions	Geriatrics/ Internal Medicine
member	MD	VP, Medical Policy & Ops	Medical Policy and Operations	Family Medicine
member	MD, MBA	Senior Director, Medical Health Service	Territories	Family Medicine
member	MD	Senior Medical Director	Medical Policy and Operations	Obstetrics & Gynecology
member	MD	Senior Director, Clinical Policy Research & Development	Office of the CMO	General Practice
member	MD, MSc, CPE	Medical Director	Active Health	Family Medicine
member	MMM, MD, CPE, DFAPA	Medical Director, Behavioral Health	Behavioral Health	Psychiatry
member	MD, MBA	Medical Director	Medical Policy and Operations	Obstetrics & Gynecology
member	MD	Medical Director	National Accounts Care Management Solutions Team	Family Medicine
member	MD	Senior Medical Director, Medical Health Service	National Accounts Care Management Solutions Team	Family Medicine/ Geriatrics

Role	Credentials	Job Title	Organization	Board Certified Specialty
member	MD	Medical Director	National Accounts Care Management Solutions Team	Occupational Medicine/ Internal Medicine/ Public Health & Gen'l Preventive
member	MD, MBA	Chief Medical Officer, Aetna Student Health	Student Health	Family Medicine
member	MD	Sr Dir, Clinical Solutions MD	Territories	Internal Medicine
member	MD	VP, Clinical Quality	Office of the CMO	Family Medicine

Appendix 4

Mental Health Parity Task Force Composition

<u>Role</u>	<u>Title of Participant</u>	<u>Organization/Department</u>
Chair	Senior Manager	Behavioral Health Product Strategy Engagement
Member	Director, Network	Behavioral Health Network Management
Member	Director, Clinical Health Services	Behavioral Health Clinical Health Services
Member	Executive Director, Network	Behavioral Health Regional Network Management
Member	Manager	Behavioral Health Clinical Health Services
Member	Analyst, Quality Management	Behavioral Health Care Quality Management
Member	Senior Project Manager	Behavioral Health Precertification
Member	Senior Medical Director	Behavioral Health Product
Member	Senior Director, Quality Management	Behavioral Health Strategy and Business Development
Member	Vice President, EAP and Chief Psychiatric Officer	Behavioral Health
Member	Senior Clinical Solutions MD	AMA AZ Medical Management
Member	Senior Director, Counsel	Behavioral Health Law Provider Networks
Member	Manager, Quality Management	Behavioral Health Care Quality Management
Member	Senior Director, Clinical Health Services	Behavioral Health Clinical Health Services
Member	Actuary	Behavioral Health Actuary

Appendix 5

Medical OP All Other OON and Duration Claims Data

Sum of Billed Amount Calendar Year 2019			
COST_CATEGORY	Non-Par	Par	Grand Total
002:Ambulatory Facility	4.63%	95.37%	100.00%
006:Radiology	3.43%	96.57%	100.00%
007:Lab	7.34%	92.66%	100.00%
008:Home Health	8.39%	91.61%	100.00%
Gastric Bypass	35.23%	64.77%	100.00%
Home Health Care	12.87%	87.13%	100.00%
Hospice	12.76%	87.24%	100.00%
Skilled Nursing	32.52%	67.48%	100.00%
Grand Total	5.28%	94.72%	100.00%

Visits per member Calendar Year 2019	
COST_CATEGORY	Visits Per Member
002:Ambulatory Facility	3.0
006:Radiology	2.8
007:Lab	3.2
008:Home Health	3.4
Gastric Bypass	1.7
Home Health Care	15.4
Hospice	8.1
Skilled Nursing	37.1
Grand Total	3.1

*The data above is based on 2019 data because it's data that aligns to the time frame (late 2018) when the NQTL analysis was revised to include more objective factors for why services are subject to an NQTL.

Appendix 6

BH OP All Other OON and Duration Claims Data

Benefit	Total Visits	Non Par Visits	Percentage Non Par	Unique member count - Non Par	Average Duration of course of treatment - Non Par	Par Visits	Percentage Par	Unique member count - Par	Average Duration of course of treatment - Par	Total Unique member count (Par & Non-Par)	Total Average Duration of course of Treatment (Par & Non-Par)
Applied Behavior Analysis (ABA)	921380	142905	15.50%	25545	5.6	778475	84.50%	23580	33.0	49125	18.76
Psychiatric & SUD Home Care Services (BHC)	29359	23500	80.00%	4090	5.8	5859	20.00%	1192	4.9	5282	5.56
Electroconvulsive therapy (ECT)	30213	3499	11.60%	2258	1.6	26714	88.40%	2332	11.5	4590	6.58
Psychiatric & SUD Intensive Outpatient (IOP)	491958	155198	31.50%	33612	4.6	336760	68.50%	29363	11.5	62975	7.81
23 Hour Observation (OBS)	4483	335	7.40%	2782	0.1	4148	93.60%	2887	1.4	5669	0.79
Outpatient Detox (OPD)	36323	12330	33.90%	2431	5.1	23993	66.10%	2115	11.3	4546	7.99
Psychiatric & SUD Partial Hospitalization (PHP)	339368	122845	36.20%	22165	5.5	216523	63.80%	19364	11.2	41529	8.17
Psychological/Neuropsychological testing (PTS)	98550	17178	17.40%	31739	0.5	81372	82.60%	27307	3.0	59046	1.67
Substance use disorder injectables (SUD)	560	53	9.50%	451	0.1	507	90.50%	466	1.1	917	0.61
Transcranial magnetic stimulation (TMS)	82786	15459	18.70%	4897	3.2	67327	81.30%	4174	16.1	9071	9.13

*The data above is based on 2019 data because it's data that aligns to the time frame (late 2018) when the NQTL analysis was revised to include more objective factors for why services are subject to an NQTL.

Appendix 7

2021 MHP Utilization Report

2021 Commercial Book of Business – Precertification

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Percent Admin Denied	Total MedNec Denied	Percent MedNec Denied	Avg TAT (Days)
IP Precert	BH	Non-Par	Behavioral	1,349	195	14.5%	169	12.5%	26	1.9%	0.4
			Detoxification	2,542	189	7.4%	118	4.6%	71	2.8%	0.6
			Drug/Alcohol Rehabilitation	1,697	136	8.0%	77	4.5%	59	3.5%	0.6
			Inpatient	859	177	20.6%	107	12.5%	70	8.1%	0.6
IP Precert	BH	Non-Par		6,447	697	10.8%	471	7.3%	226	3.5%	0.5
		Par	Behavioral	37,439	780	2.1%	731	2.0%	49	0.1%	0.1
			Detoxification	9,973	362	3.6%	228	2.3%	134	1.3%	0.3
			Drug/Alcohol Rehabilitation	7,078	265	3.7%	120	1.7%	145	2.0%	0.5
			Inpatient	3,109	216	6.9%	112	3.6%	104	3.3%	0.4
			Medical	15	8	53.3%	8	53.3%	0	0.0%	0.5
IP Precert	BH	Par		57,614	1,631	2.8%	1,199	2.1%	432	0.7%	0.4
	Med	Non-Par	Detained Baby	6	3	50.0%	3	50.0%	0	0.0%	1.2
			High Risk Pregnancy	4	0	0.0%	0	0.0%	0	0.0%	0.3
			Inpatient	16	0	0.0%	0	0.0%	0	0.0%	0.4
			LTAC	50	22	44.0%	3	6.0%	19	38.0%	2.4
			Maternity	40	14	35.0%	13	32.5%	1	2.5%	2.0
			Medical	15,370	12,464	81.1%	12,034	78.3%	430	2.8%	0.6
			Neonatal ICU	73	14	19.2%	13	17.8%	1	1.4%	3.0
			Rehabilitation	145	69	47.6%	52	35.9%	17	11.7%	1.7
			Skilled Nursing Care	300	155	51.7%	119	39.7%	36	12.0%	2.0
			Surgical	631	229	36.3%	158	25.0%	71	11.3%	3.9

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Percent Admin Denied	Total MedNec Denied	Percent MedNec Denied	Avg TAT (Days)
			Transplant	12	1	8.3%	0	0.0%	1	8.3%	0.4
IP Precert	Med	Non-Par		16,647	12,971	77.9%	12,395	74.5%	576	3.5%	1.6

		Par	Detained Baby	1,231	256	20.8%	184	14.9%	72	5.8%	1.7
			High Risk Pregnancy	1,070	276	25.8%	166	15.5%	110	10.3%	0.7
			Inpatient	400	4	1.0%	4	1.0%	0	0.0%	0.0
			LTAC	2,202	812	36.9%	64	2.9%	748	34.0%	1.5
			Maternity	4,684	869	18.6%	754	16.1%	115	2.5%	1.5
			Medical	321,915	102,492	31.8%	70,826	22.0%	31,666	9.8%	0.8
			Neonatal ICU	11,725	1,766	15.1%	1,601	13.7%	165	1.4%	1.6
			Rehabilitation	9,392	1,672	17.8%	279	3.0%	1,393	14.8%	1.2
			Skilled Nursing Care	7,826	1,354	17.3%	444	5.7%	910	11.6%	1.2
			Surgical	21,053	3,357	15.9%	1,113	5.3%	2,244	10.7%	3.5
			Transition of Care	29	0	0.0%	0	0.0%	0	0.0%	3.0
			Transplant	1,330	35	2.6%	32	2.4%	3	0.2%	0.8
IP Precert	Med	Par		382,857	112,893	29.5%	75,467	19.7%	37,426	9.8%	1.5

IP Precert				463,565	128,192	27.7%	89,532	19.3%	38,660	8.3%	1.2
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IP Precert				463,565	128,192	27.7%	89,532	19.3%	38,660	8.3%	1.2
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OP Precert	BH	Non-Par	Chemical Dependency Intensive Outpatient	79	27	34.2%	15	19.0%	12	15.2%	2.4
			Chemical Dependency Outpatient	7	0	0.0%	0	0.0%	0	0.0%	1.7
			Chemical Dependency Partial Day Hospital	3,063	105	3.4%	70	2.3%	35	1.1%	0.9
			ECT Outpatient	1	0	0.0%	0	0.0%	0	0.0%	1.0
			Mental Health Intensive Outpatient	174	39	22.4%	11	6.3%	28	16.1%	3.0
			Mental Health Outpatient	7,485	1,317	17.6%	452	6.0%	865	11.6%	4.4

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Percent Admin Denied	Total MedNec Denied	Percent MedNec Denied	Avg TAT (Days)
			Mental Health Partial Day Hospital	1,401	68	4.9%	31	2.2%	37	2.6%	0.8
			Non Par	19,946	1,763	8.8%	1,153	5.8%	610	3.1%	3.6
			Psychological Testing	71	18	25.4%	16	22.5%	2	2.8%	8.2
			Transition of Care	1,186	174	14.7%	165	13.9%	9	0.8%	2.5
OP Precert	BH	Non-Par		33,413	3,511	10.5%	1,913	5.7%	1,598	4.8%	2.9

		Par	Chemical Dependency Intensive Outpatient	87	23	26.4%	6	6.9%	17	19.5%	0.7
			Chemical Dependency Outpatient	8	0	0.0%	0	0.0%	0	0.0%	0.0
			Chemical Dependency Partial Day Hospital	5,517	104	1.9%	50	0.9%	54	1.0%	0.7
			ECT Outpatient	5	0	0.0%	0	0.0%	0	0.0%	0.0
			Medical	11	4	36.4%	0	0.0%	4	36.4%	3.7
			Mental Health Intensive Outpatient	280	35	12.5%	17	6.1%	18	6.4%	1.8
			Mental Health Outpatient	49,337	6,173	12.5%	2,091	4.2%	4,082	8.3%	4.2
			Mental Health Partial Day Hospital	12,636	128	1.0%	67	0.5%	61	0.5%	0.6
			Psychological Testing	69	5	7.2%	5	7.2%	0	0.0%	1.9
			Transition of Care	168	26	15.5%	23	13.7%	3	1.8%	4.9
OP Precert	BH	Par		68,118	6,498	9.5%	2,259	3.3%	4,239	6.2%	1.9

	Med	Non-Par	Chemical Dependency Outpatient	6	6	100.0%	6	100.0%	0	0.0%	0.0
			Durable Medical Equipment	316	83	26.3%	4	1.3%	79	25.0%	7.5
			Home Care	134	40	29.9%	16	11.9%	24	17.9%	3.8
			Medical	4,784	1,629	34.1%	640	13.4%	989	20.7%	3.7
			Mental Health Intensive Outpatient	2	0	0.0%	0	0.0%	0	0.0%	0.0
			NME	18	0	0.0%	0	0.0%	0	0.0%	2.6
			Non Par	35,998	9,930	27.6%	2,438	6.8%	7,492	20.8%	5.8
			PDN in the home	176	144	81.8%	67	38.1%	77	43.8%	6.4

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Percent Admin Denied	Total MedNec Denied	Percent MedNec Denied	Avg TAT (Days)
			Psychological Testing	7	2	28.6%	0	0.0%	2	28.6%	2.1
			Surgical	6,846	1,502	21.9%	323	4.7%	1,179	17.2%	4.3
			Transition of Care	2,549	454	17.8%	198	7.8%	256	10.0%	5.4
OP Precert	Med	Non-Par		50,836	13,790	27.1%	3,692	7.3%	10,098	19.9%	3.8

		Par	Durable Medical Equipment	10,456	1,840	17.6%	241	2.3%	1,599	15.3%	7.0
			Home Care	1,558	415	26.6%	122	7.8%	293	18.8%	3.6
			Medical	177,218	43,592	24.6%	16,074	9.1%	27,518	15.5%	2.9
			Mental Health Intensive Outpatient	61	1	1.6%	1	1.6%	0	0.0%	0.0
			NME	511	2	0.4%	1	0.2%	1	0.2%	0.7
			PDN in the home	2,376	1,950	82.1%	528	22.2%	1,422	59.8%	6.9
			Psychological Testing	7	0	0.0%	0	0.0%	0	0.0%	2.7
			Surgical	176,472	28,360	16.1%	3,136	1.8%	25,224	14.3%	4.6
			Transition of Care	2,414	287	11.9%	100	4.1%	187	7.7%	5.8
OP Precert	Med	Par		371,073	76,447	20.6%	20,203	5.4%	56,244	15.2%	3.8

OP Precert				523,440	100,246	19.2%	28,067	5.4%	72,179	13.8%	3.1
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OP Precert				523,440	100,246	19.2%	28,067	5.4%	72,179	13.8%	3.1
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2021 Commercial Book of Business – Concurrent Review

								Admin/MedNec Denials			
Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Percent Admin Denied	Total MedNec Denied	Percent MedNec Denied	Avg TAT (Days)
IP Concurrent	BH	Non-Par	Behavioral	932	84	9.0%	40	4.3%	44	4.7%	0.2
			Detoxification	1,005	89	8.9%	69	6.9%	20	2.0%	0.5
			Drug/Alcohol Rehabilitation	4,407	213	4.8%	44	1.0%	169	3.8%	0.2
			Inpatient	2,113	211	10.0%	10	0.5%	201	9.5%	0.3
IP Concurrent	BH	Non-Par		8,457	597	7.1%	163	1.9%	434	5.1%	0.3
		Par	Behavioral	24,159	1,019	4.2%	771	3.2%	248	1.0%	0.1
			Detoxification	4,290	241	5.6%	181	4.2%	60	1.4%	0.5
			Drug/Alcohol Rehabilitation	16,568	626	3.8%	155	0.9%	471	2.8%	0.2
			Inpatient	10,057	581	5.8%	50	0.5%	531	5.3%	0.2
			Medical	4	1	25.0%	1	25.0%	0	0.0%	0.5
IP Concurrent	BH	Par		55,078	2,468	4.5%	1,158	2.1%	1,310	2.4%	0.3
	Med	Non-Par	Detained Baby	2	0	0.0%	0	0.0%	0	0.0%	0.0
			High Risk Pregnancy	2	1	50.0%	1	50.0%	0	0.0%	0.0
			Inpatient	1	0	0.0%	0	0.0%	0	0.0%	0.0
			LTAC	60	4	6.7%	1	1.7%	3	5.0%	0.2
			Maternity	20	4	20.0%	4	20.0%	0	0.0%	2.9
			Medical	3,345	643	19.2%	410	12.3%	233	7.0%	0.7
			Neonatal ICU	147	12	8.2%	12	8.2%	0	0.0%	0.5
			Rehabilitation	119	12	10.1%	3	2.5%	9	7.6%	0.3
			Skilled Nursing Care	299	86	28.8%	44	14.7%	42	14.0%	0.4
			Surgical	1,388	565	40.7%	294	21.2%	271	19.5%	4.0
			Transplant	34	3	8.8%	0	0.0%	3	8.8%	0.4

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Admin/MedNec Denials			
								Percent Admin Denied	Total MedNec Denied	Percent MedNec Denied	Avg TAT (Days)
IP Concurrent	Med	Non-Par		5,417	1,330	24.6%	769	14.2%	561	10.4%	0.8
		Par	Detained Baby	574	40	7.0%	36	6.3%	4	0.7%	0.4
			High Risk Pregnancy	846	54	6.4%	45	5.3%	9	1.1%	0.1
			Inpatient	52	0	0.0%	0	0.0%	0	0.0%	0.1
			LTAC	4,425	492	11.1%	215	4.9%	277	6.3%	0.2
			Maternity	1,470	138	9.4%	116	7.9%	22	1.5%	0.6
			Medical	195,184	21,488	11.0%	15,827	8.1%	5,661	2.9%	0.4
			Neonatal ICU	19,357	1,368	7.1%	1,253	6.5%	115	0.6%	0.3
			Rehabilitation	13,466	1,516	11.3%	589	4.4%	927	6.9%	0.2
			Skilled Nursing Care	17,448	3,313	19.0%	1,102	6.3%	2,211	12.7%	0.2
			Surgical	67,554	12,489	18.5%	3,140	4.6%	9,349	13.8%	3.2
			Transition of Care	59	0	0.0%	0	0.0%	0	0.0%	0.9
			Transplant	4,431	41	0.9%	39	0.9%	2	0.0%	0.7
IP Concurrent	Med	Par		324,866	40,939	12.6%	22,362	6.9%	18,577	5.7%	0.6
IP Concurrent				393,818	45,334	11.5%	24,452	6.2%	20,882	5.3%	0.6
IP Concurrent				393,818	45,334	11.5%	24,452	6.2%	20,882	5.3%	0.6
OP Concurrent	BH	Non-Par	Chemical Dependency Intensive Outpatient	53	4	7.5%	0	0.0%	4	7.5%	3.8
			Chemical Dependency Outpatient	2	0	0.0%	0	0.0%	0	0.0%	0.0
			Chemical Dependency Partial Day Hospital	1,517	108	7.1%	37	2.4%	71	4.7%	0.3
			ECT Outpatient	1	0	0.0%	0	0.0%	0	0.0%	0.0
			Mental Health Intensive Outpatient	101	4	4.0%	1	1.0%	3	3.0%	0.2
			Mental Health Outpatient	4,870	1,046	21.5%	165	3.4%	881	18.1%	3.6

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Admin/MedNec Denials			
								Percent Admin Denied	Category	BH/Med	Par/Non-Par
			Mental Health Partial Day Hospital	1,340	129	9.6%	31	2.3%	98	7.3%	0.5
			Non Par	4,548	445	9.8%	80	1.8%	365	8.0%	2.0
			Psychological Testing	6	0	0.0%	0	0.0%	0	0.0%	4.0
			Transition of Care	53	6	11.3%	6	11.3%	0	0.0%	0.6
OP Concurrent	BH	Non-Par		12,491	1,742	13.9%	320	2.6%	1,422	11.4%	1.5

		Par	Chemical Dependency Intensive Outpatient	43	3	7.0%	1	2.3%	2	4.7%	0.4
			Chemical Dependency Outpatient	13	0	0.0%	0	0.0%	0	0.0%	2.5
			Chemical Dependency Partial Day Hospital	2,928	252	8.6%	78	2.7%	174	5.9%	0.3
			Medical	8	0	0.0%	0	0.0%	0	0.0%	0.5
			Mental Health Intensive Outpatient	291	45	15.5%	21	7.2%	24	8.2%	3.1
			Mental Health Outpatient	46,349	5,553	12.0%	992	2.1%	4,561	9.8%	3.8
			Mental Health Partial Day Hospital	7,649	228	3.0%	81	1.1%	147	1.9%	0.3
			Transition of Care	20	11	55.0%	0	0.0%	11	55.0%	0.7
OP Concurrent	BH	Par		57,301	6,092	10.6%	1,173	2.0%	4,919	8.6%	1.4

	Med	Non-Par	Durable Medical Equipment	18	13	72.2%	0	0.0%	13	72.2%	0.2
			Home Care	9	5	55.6%	5	55.6%	0	0.0%	0.3
			Medical	303	106	35.0%	46	15.2%	60	19.8%	2.2
			Mental Health Intensive Outpatient	1	0	0.0%	0	0.0%	0	0.0%	0.0
			NME	28	0	0.0%	0	0.0%	0	0.0%	0.2
			Non Par	2,030	340	16.7%	67	3.3%	273	13.4%	1.6
			PDN in the home	33	27	81.8%	6	18.2%	21	63.6%	2.1
			Psychological Testing	2	0	0.0%	0	0.0%	0	0.0%	0.0
			Surgical	250	42	16.8%	1	0.4%	41	16.4%	1.4
			Transition of Care	56	0	0.0%	0	0.0%	0	0.0%	0.2

Category	BH/Med	Par/Non-Par	Stay Type	Total	Total Denied	Percent Denied	Total Admin Denied	Admin/MedNec Denials			
								Percent Admin Denied	Category	BH/Med	Par/Non-Par
OP Concurrent	Med	Non-Par		2,730	533	19.5%	125	4.6%	408	14.9%	0.8
		Par	Durable Medical Equipment	1,499	260	17.3%	12	0.8%	248	16.5%	2.4
			Home Care	268	12	4.5%	2	0.7%	10	3.7%	2.3
			Medical	10,306	3,020	29.3%	1,042	10.1%	1,978	19.2%	1.1
			NME	1,581	0	0.0%	0	0.0%	0	0.0%	0.3
			PDN in the home	218	127	58.3%	42	19.3%	85	39.0%	2.0
			Surgical	6,963	1,340	19.2%	123	1.8%	1,217	17.5%	1.1
			Transition of Care	68	13	19.1%	1	1.5%	12	17.6%	0.8
OP Concurrent	Med	Par		20,903	4,772	22.8%	1,222	5.8%	3,550	17.0%	1.4
OP Concurrent				93,425	13,139	14.1%	2,840	3.0%	10,299	11.0%	1.3
OP Concurrent				93,425	13,139	14.1%	2,840	3.0%	10,299	11.0%	1.3

2021 Commercial Book of Business – Average Length of Stay (LOS)

Category	BH/Med	Par/Non-Par	Stay Type	Total	Avg LOS
IP	BH	Non-Par	Behavioral	1,368	9.7
			Detoxification	2,643	11.7
			Drug/Alcohol Rehabilitation	2,760	20.3
			Inpatient	1,015	28.1
IP	BH	Non-Par		7,786	16.5
		Par	Behavioral	38,037	8.1
			Detoxification	10,469	12.2
			Drug/Alcohol Rehabilitation	11,296	20.3
			Inpatient	4,028	34.4
			Medical	16	1.3
IP	BH	Par		63,846	12.6
	Med	Non-Par	Detained Baby	6	5.2
			High Risk Pregnancy	5	6.6
			Inpatient	16	24.7
			LTAC	49	15.1
			Maternity	43	5.2
			Medical	15,371	2.0
			Neonatal ICU	70	32.8
			Rehabilitation	153	9.1
			Skilled Nursing Care	308	18.3
			Surgical	523	2.8
			Transplant	15	20.5
IP	Med	Non-Par		16,559	2.6
		Par	Detained Baby	1,261	9.0
			High Risk Pregnancy	1,110	6.4
			Inpatient	420	40.6
			LTAC	2,272	18.4

Category	BH/Med	Par/Non-Par	Stay Type	Total	Avg LOS
			Maternity	4,760	4.3
			Medical	325,186	4.6
			Neonatal ICU	12,065	19.3
			Rehabilitation	9,779	13.2
			Skilled Nursing Care	8,381	17.8
			Surgical	23,573	3.3
			Transition of Care	9	7.3
			Transplant	1,426	16.9
IP	Med	Par		390,242	5.6
IP				478,433	6.6
IP				478,433	6.6

*The data above is refreshed second quarter of every year for the most recently closed calendar year. This data represents all fully insured commercial business.

APPENDIX 8

Outpatient Services

Please note:

- *The responses below included data for initial applications. The below is based on National level data.*
- *Aetna does not track credentialed providers by Inpatient vs. Outpatient. A provider may be a provider that practices in a facility (i.e., surgery center), but also sees patients at their office. The outpatient data below reflects credentialing information/data for providers who are office based.*
- Please provide a comparison of the application process for MH/SUD and MS providers, including:
 - the number of applications received, accepted or denied/withdrawn.

Applications	MH/SUD	MS
Received	29,510	31,728
Accepted	29,491	31,696
Denied/Withdrawn	19	32
% Approved	99.9%	99.9%

- The average number of days from receipt of a completed credentialing application to approval to be contracted (2021).

MS Providers: 31 Days MH/SUD Providers: 21 Days

- The number of times additional documentation has been requested to establish credentialing standards are met.

Aetna is unable to report the number of times additional documentation may be requested to establish credentialing standards are met. Aetna will follow with providers as part of the credentialing process as needed. Examples would include, but not be limited to incomplete applications, missing information (i.e., licensure, liability insurance, etc.). During 2021, there were also providers that were not able to provide information for recredentialing due to office or state closure related to Covid-19.

APPENDIX 9

Inpatient Services

Please note:

- ***The responses below included data for initial applications. The below is based on National level data.***
- ***Aetna does not track credentialed providers by Inpatient vs. Outpatient. A provider may be a provider that practices in a facility (i.e., surgery center), but also sees patients at their office. The inpatient data below reflects Facility credentialing information/data.***
- Please provide a comparison of the application process for MH/SUD and MS providers, including:
 - The number of applications received; accepted, denied/withdrawn;

Applications	MH/SUD	MS
Received	1060	2607
Accepted	1011	2474
Denied/Withdrawn	49	133
% Approved	95.3%	94.8%

- The length of time to process the application;

Aetna does not produce a report that shows the length of time to process a credentialing application for facilities broken out by MH/SUD vs MS. Aetna’s initial credentialing turnaround time for all facilities is an average of 18 calendar days from receipt of a completed credentialing application to approval to be contracted.

- The number of times additional documentation has been requested to establish credentialing standards are met.

Aetna is unable to report the number of times additional documentation may be requested to establish credentialing standards are met. Aetna will follow with facilities as part

of the credentialing process as needed. Examples would include, but not be limited to incomplete applications, missing information (i.e., licensure, liability insurance, etc.). During 2021, there were also facilities that were not able to provide information for recredentialing due to facility or state closure related to Covid-19.