

2026 Nonquantitative Treatment Limitation (NQTL) Submission Template

Instructions: This NQTL reporting submission form includes the required six information elements or Required Steps as specified by the Mental Health Parity and Addiction Equity Act (MHPAEA) and its regulations, including 42 USC Section 300gg-26(a)(8)(A) and 45 CFR 146.137. The comparative analyses to be performed must be reported using this submission form and should comply with MHPAEA, its regulations, federal guidance, and the instructions, both separately provided and set forth herein.

A separate reporting form should be prepared and completed for each NQTL requested by the BOI in each benefits classification/sub-classification. For example, the comparative analysis for prior authorization for the Inpatient, In-Network benefits classification should be provided on its own reporting submission form, and the comparative analysis for prior authorization for the Inpatient, Out-of-Network classification should be provided in a separate reporting submission form. Similarly, the comparative analyses for prior authorization for Outpatient benefits should be reported separately, with a form used for In-Network and a form to be used for Out-of-Network. If there are questions about how to properly report using this form, please contact the BOI.

Prescription Drug Benefits – Prior Authorization, Step Therapy, and Quantity

Step 1: Description of the Nonquantitative treatment limitation (NQTL).

See [45 CFR 146.137\(c\)\(1\)](#). Step 1 must include the following:

- (i) Identification of the NQTL, including the specific terms of the plan or coverage or other relevant terms regarding the NQTL, the policies or guidelines (internal or external) in which the NQTL appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the NQTL;
- (ii) Identification of all mental health (MH) and substance use disorder (SUD) benefits and medical/surgical benefits to which the NQTL applies, including a list of which benefits are considered MH or SUD benefits and which benefits are medical/surgical benefits; and
- (iii) A description of which benefits are included in each classification set forth in Section 146.136(c)(2)(ii)(A).

See also [FAQ 45](#) (Q2, #'s 1 and 2) guidance. This guidance stipulates that a sufficient analysis should include:

- A clear description of the specific NQTL, plan terms, and policies at issue; and
- Identification of the specific MH/SUD and medical/surgical benefits to which the NQTL applies within each benefit classification, and a clear statement as to which benefits identified are treated as MH/SUD and which are treated as medical/surgical.

Issuer Response:

This NQTL comparative analysis describes the following benefit classification: Prescription Drug Benefits.

Prior authorization, quantity limits, and step therapy are each considered a non-quantitative treatment limitation (“NQTL”) under the Mental Health Parity and Addiction Equity Act of 2008 (“MHPAEA”) and its implementing regulations and sub-regulatory guidance. In the review and analysis of the Prescription Drug Benefits – Prior Authorization, Step Therapy, and Quantity Limits NQTL, Cigna reviewed policies applicable to Cigna, Evernorth Behavioral Health (EBH), and Connect Bronze 6500 Indiv Med Deductible plan certificate.

This document represents an NQTL comparative analysis for prior authorization and step therapy applied to mental health/substance use disorder (“MH/SUD”) and/or medical/surgical (“M/S”) services for the prescription drug benefit classification and is incorporated into plans offered by Cigna Health and Life Insurance Company (“CHLIC”)

In the review and analysis of the prior authorization (PA), quantity limits (QL), and step therapy (ST) NQTLs, Cigna reviewed summary plan documents and benefit descriptions, conducted multiple discussions with its Pharmacy teams. No third parties or separate related entities played a role in developing the NQTL, its comparative analysis, or the policies and procedures contained in this response.

The plan language or coverage terms governing Prescription Drug is excerpted from the Connect Bronze 6500 Indiv Med Deductible plan certificate and states as follows:

Connect Bronze 6500 Indiv Med Deductible Plan Language
Prescription Drugs Covered under the Medical Benefits When Prescription Drugs on Cigna Healthcare’s Prescription Drug List or on the Cigna Pathwell Specialty Medication Drug List are administered in a health care setting by a Physician or Other Health Care Professional, and are billed with the office or facility charges, they will be covered under the medical benefits of this Policy. These medications may still be subject to Prior Authorization or Step Therapy requirements. Limited Distribution Drugs For certain Limited Distribution Drugs covered under the medical benefits of this Policy, the Provider who administers the drug must obtain the drug directly from Accredo, Cigna Healthcare’s preferred specialty Pharmacy, or if not available through Accredo then through a network specialty Pharmacy, in order for that drug to be covered. If you have questions about where your Provider obtained the drugs being administered to you, please consult your Provider. Specialty Medications that require administration through the Cigna Pathwell Specialty Network Certain Specialty Medications often used for the treatment of complex conditions that are high cost, require special handling and administration, Provider coordination, or patient education may be subject to additional

coverage criteria or require administration by a Participating Provider in the Cigna Pathwell Specialty Network. Cigna determines which injections, infusions, and implantable drugs are subject to these criteria and requirements.

A complete list of these Specialty Medications subject to additional coverage criteria or that require administration by a Participating Provider in the Cigna Pathwell Specialty Network is available at www.cigna.com/pathwellspecialty.

The following are not covered, unless a medical necessity coverage exception is obtained:

- Specialty Medication regimens that have a therapeutic equivalent or therapeutic alternative to another covered Prescription Drug(s);
- Specialty Medications newly approved by the Food and Drug Administration (FDA) following its market launch while clinical and business analyses are completed;
- Specialty Medication regimens for which there is an appropriate lower cost alternative for treatment.

Cigna may consider certain Specialty Medication regimens as preferred when they are clinically superior to alternative treatments and more cost effective. Preferred regimens may be required for coverage, except when the Insured Person is not a candidate for the regimen and a medical necessity coverage exception is obtained. Certain Specialty Medications may be covered only under the Prescription Drug benefits of this Policy when one or more of the following criteria is met:

- Cost of the medication is lower under Pharmacy sources than medical sources in the Cigna Pathwell Specialty Network;
- Provider accepts the medication from the Pharmacy source;
- The Insured Person is able to self-administer the medication procured from a Pharmacy.

Medications Covered under the Medical Benefits

Infusion and Injectable Medications on Cigna Healthcare's Prescription Drug List are covered under the medical benefits of this Policy when they are administered in a healthcare setting by a Physician or Other Health Care Professional, and are billed with the office or facility charges.

You or your Physician can view the Cigna Healthcare Prescription Drug List by:

- accessing www.cigna.com/ifp-drug-lists, and
- choose your state.

Note: the drugs may be subject to Prescription Drug Prior Authorization or Step Therapy requirements.

Prescription Drug List Management

The Prescription Drug List is managed by the Health Plan Value Assessment Committee (HVAC), which makes, subject to the P&T Committee's review and approval of the Prescription Drug List, coverage tier placement decisions of Prescription Drugs or Related Supplies and/or applies utilization management requirements to certain Prescription Drugs or Related Supplies. The Prescription Drug List is reviewed and revised at least once annually but may also change periodically during the Year for various reasons. Your Policy's coverage tiers may contain Prescription Drugs or Related Supplies that are Generic Drugs, Brand Name Drugs or Specialty Medications. Placement of any Prescription Drug or Related Supplies in a specific tier, and application of utilization management requirements to a Prescription Drug, depends on a number of clinical and economic factors. Clinical factors include, without limitation, the P&T Committee's evaluations of the place in therapy, or relative safety or relative efficacy of the Prescription Drug or Related Supplies, and economic factors include, without limitation, the cost and/or available rebates for Prescription Drugs or Related Supplies. Whether a particular Prescription Drug or Related Supply is appropriate for You or any of Your Family Member(s), regardless of its eligibility coverage under Your Policy, is a determination that is made by You (or Your Family Member) and the prescribing Physician.

The coverage status of a Prescription Drug or Related Supply may change periodically during the Year for various reasons. For example, a Prescription Drug or Related Supply may be removed from the market, a new Prescription Drug in the same therapeutic class may become available, or the cost of a Prescription Drug or Related Supply may increase.

As a result of coverage changes, you may be required to pay more or less for that Prescription Drug or Related

Supply, or try another covered Prescription Drug or Related Supply. Please access www.mycigna.com through the Internet or call Customer Service at the telephone number on your ID card for the most up-to-date coverage tier status, utilization management, or other coverage limitations for Prescription Drugs or Related Supplies. We will inform you not less than 30 days' prior written notice of a change to a Prescription Drug List that results in the movement of a Prescription Drug to a tier with higher cost sharing requirements unless the change occurs at the time of coverage renewal.

Covered Expenses

If an Insured Person, while covered under this Policy, incurs expenses for charges made by a Pharmacy, for Medically Necessary Prescription Drugs or Related Supplies ordered by a Physician, Cigna Healthcare will provide coverage for those expenses as shown in the benefit schedule. Coverage also includes Medically Necessary Prescription Drugs and Related Supplies dispensed for a Prescription issued to You or Your Family Members by a licensed dentist for the prevention of infection or pain in conjunction with a dental procedure. When You or Your Family Members are issued a Prescription for Medically Necessary Prescription Drugs or Related Supplies as part of the rendering of Emergency Services and that Prescription cannot reasonably be filled by a Participating Pharmacy, the Prescription will be covered by Cigna Healthcare, as if filled by a Participating Pharmacy.¹

Medication Synchronization

Cigna Healthcare will allow and apply a prorated daily Cost Share rate to Prescription Drugs that are dispensed by a Participating Pharmacy for a partial supply if the prescribing Physician or the pharmacist determines the fill or refill to be in the best interest of the Insured Person and he/she requests or agrees to a partial supply for the purpose of synchronizing his/her medications, provided that such a proration for any Prescription Drug does not occur more frequently than once a Year.

Prior Authorization, Exception and Appeal Process for Prescription Drugs and Related Supplies

Prior Authorization from Cigna Healthcare is required for certain Prescription Drugs and Related Supplies, meaning that your Physician must obtain Prior Authorization from Cigna Healthcare before the Prescription Drug or Related Supply will be covered.

Prior Authorization

When your Physician prescribes certain Prescription Drugs or Related Supplies, including high cost and Specialty Medications, Cigna Healthcare requires your Physician to obtain Prior Authorization before the Prescription or supply can be filled. To obtain Prior Authorization, your Physician must follow the Prescription Drug and Related Supply Prior Authorization and Exception Request Process as described below.

Step Therapy

Step Therapy is a type of Prior Authorization. Cigna Healthcare may require an Insured Person to follow certain steps before covering some Prescription Drugs and Related Supplies, including some higher-cost and Specialty Medications. If a Prescription Drug or Related Supply is subject to a Step Therapy requirement, then you must try one or more similar Prescription Drugs and Related Supplies before the Policy will cover the requested Prescription Drug or Related Supply. The Prescription Drugs and Related Supplies that require Step Therapy can be identified on the Prescription Drug List at www.mycigna.com. To obtain Step Therapy Prior Authorization, your Physician must follow the Prescription Drug and Related Supply Prior Authorization and Exception Request Process as described below.

Exceptions for Prescription Drugs and Related Supplies Not on the Prescription Drug List

If your Physician prescribes a Prescription Drug or Related Supply that is not on Cigna Healthcare's Prescription Drug List, he or she can request that Cigna Healthcare make an exception and agree to cover that drug or supply for your condition. To obtain an exception for a Prescription Drug or Related Supply, your Physician must follow the Prescription Drug and Related Supply Prior Authorization and Exception Request Process as described below.

Prescription Drug and Related Supply Prior Authorization and Exception Request Process

¹ Connect Bronze 6500 Indiv Med Deductible Plan Booklet pgs. 77-80 of 112

To obtain an exception, you or your Physician may call Cigna Healthcare, or complete the appropriate form and fax it to Cigna Healthcare to request an exception. Your Physician can certify in writing that:

- You have previously used a Prescription Drug or Related Supply that is on Cigna Healthcare's Prescription Drug List or in a Step Therapy Protocol, and the Prescription Drug or Related Supply has been detrimental to your health or has been ineffective in treating your condition and, in the opinion of your Physician, is likely to again be detrimental to your health or ineffective in treating the condition; or
- You have tried the Step Therapy-required Prescription Drug while under your current or previous health plan, and the Prescription Drug was discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- If you are currently receiving a positive therapeutic outcome on a Prescription Drug recommended by your Physician for the medical condition under consideration while you are on the current or the immediately preceding health plan; or
- If a Step Therapy-required Prescription Drug is contraindicated.

When you or your Physician request a Prescription Drug or Related Supply exception, the exception request will be reviewed and completed by Cigna Healthcare within one business day of receipt. When you or your Physician request a Step Therapy Exception, the exception request will be reviewed and completed by Cigna Healthcare within 72 hours of receipt, including hours on weekends.

Expedited Review of a Prior Authorization, Step Therapy or Prescription Drug Exception Request

An expedited review may be requested by you or your Physician when you are suffering from a health condition that may seriously jeopardize your life, health, or ability to regain maximum function or when you are undergoing a current course of treatment using a Prescription Drug or Related Supply not on Cigna Healthcare's Prescription Drug List. When you or your Physician request a Prescription Drug, Related Supply or Step Therapy Exception, the expedited review will be reviewed and completed by Cigna Healthcare within 24 hours of receipt, including hours on weekends.

If after reasonable investigation and consultation with your Physician the medication is determined to be inappropriate therapy for your medical condition, your Physician will receive confirmation that the exception request is approved. The drug will be covered without additional cost sharing beyond that of a drug on Cigna Healthcare's Prescription Drug List. Once your Physician receives confirmation, the Prior

Authorization/exception will be processed in Cigna Healthcare's pharmacy claim system to allow you to have coverage for those Prescription Drugs or Related Supplies. The length of the Prior Authorization will be granted until you no longer use the Prescription Drug or Related Supply for which the Prior Authorization or exception was approved. When your Physician advises you that coverage for the Prescription Drugs or Related Supplies has been approved, you should contact the Pharmacy to fill the Prescription(s).

If the request is denied, you and your Physician will be notified that coverage for the Prescription Drugs or Related Supplies was not authorized.

Appeal of a Prior Authorization, Step Therapy or Prescription Drug Exception Denial

If you, a person acting on your behalf or the prescribing Physician or other prescriber disagree with a coverage decision, you, a person acting on your behalf or the prescribing Physician or other prescriber may appeal that decision in accordance with the provisions of this Policy, by submitting a written request stating why the Prescription Drugs or Related Supplies should be covered. Please see the section of this Policy entitled "When You Have a Complaint or an Appeal" which describes the process for the external independent review.

If you have questions about specific Prescription Drug List exceptions, Prior Authorization or a Step Therapy request, call Customer Service at the toll-free number on the back of your ID card.

Coverage of New Drugs

All new FDA-approved Prescription Drugs or Related Supplies (or new FDA-approved indications) will be covered under this Policy once the Cigna Health Plan Value Assessment Committee (HVAC) makes a placement decision on the new Prescription Drug or Related Supply (or new indication), which decision shall be based in part on the P&T Committee's clinical review of the drug. The Cigna Health Plan Value Assessment Committee (HVAC) will determine if the FDA-approved Prescription Drugs or Related Supplies (or new FDA-

approved indications) will be placed on the Prescription Drug List. If not placed on the Prescription Drug List, the FDA-approved Prescription Drugs or Related Supplies (or new FDA-approved indications) will be available through the Prescription Drug and Related Supply Prior Authorization and Exception Request Process outlined above.

Reimbursement/Filing a Claim

When an Insured Person purchases Prescription Drugs or Related Supplies through a retail Participating Pharmacy they pay any applicable Copayment, Coinsurance or Deductible shown in the benefit schedule at the time of purchase. The Insured Person does not need to file a claim form.

To purchase Prescription Drugs or Related Supplies from Express Scripts Pharmacy, Cigna Healthcare's home delivery Pharmacy, see the home delivery drug brochure at www.mycigna.com for details, or call the toll-free customer service number on the back of your ID card.

Claims and Customer Service

Drug claim forms are available upon written request to:

For retail Pharmacy claims:

Cigna Healthcare Pharmacy Service Center

PO Box 188053

Chattanooga TN 37422-8053

For home delivery Pharmacy claims:

Express Scripts Pharmacy

PO Box 66301

St Louis MO 66301-6301

1-800-835-3784

Forms are also available online at www.mycigna.com.

To request the forms be mailed to you call the toll-free customer service number on the back of your ID card.

The address to which you must mail paper claim forms is subject to change. Please check www.mycigna.com or call the toll-free customer service number on the back of your ID card to confirm the appropriate mailing address for any claim form you wish to send. If You or Your Family Member(s) have any questions about the Prescription Drug benefit, call the toll-free customer service number on the back of your ID card.²

Glossary:

1. **Benefit Exclusion:** means a provision of a benefit plan that excludes coverage for a drug regardless of whether the drug is "medical necessary" to treat a particular indication. For examples, a benefit plan may exclude coverage for drugs when they are used to treat sexual dysfunction, even if the drug is "medically necessary" for the customer seeking coverage for the drug. Because a drug may possess multiple FDA-approved indications, a drug may be subject to a Benefit Exclusion for one indication but covered by the benefit plan for another.
2. **Customer:** means an individual participant in a group or individual health plan, the consumer of the insurance benefit.
3. **Drug Product or Drug:** means a drug, biologic or other product that has been approved by the FDA, certain products approved under the Drug Efficacy Study Implementation review, or products marketed prior to 1938 and not subject to review and that can, under federal or state law, be dispensed only pursuant to a prescription, and certain nonprescription products. This definition includes certain diabetic supplies, inhaler assistance devices and accessories, and needles and syringes used for self-administered drugs or biologics.

4. FDA: means the U.S. Food and Drug Administration.
5. Formulary: A Formulary is the complete list offered as part of group and/or individual health plans as of a certain date that categorizes drug products that have been approved by the U.S. Food and Drug Administration ("FDA") into coverage tiers. A Prescription Drug List (PDL) is a subset of its associated Formulary as of a certain date and is public facing. A PDL is a list of the most commonly prescribed medications covered on its associated Formulary and does not show all of the medications a particular plan may cover. The terms are used interchangeably.
6. Independent Review Organization (IRO)/Review Organization: acts as a third-party medical review resource which provides objective, unbiased medical determinations that support effective decision making, based only on medical evidence. IROs deliver conflict-free decisions that help clinical and claims management professionals better allocate healthcare resources.
7. Medical Necessity: Typically, Cigna considers medical, surgical, diagnostic, psychiatric, substance abuse or other health care technologies, supplies, treatments, procedures, or devices to be medically necessary if the following criteria are met:
 - Required to diagnose or treat an illness, injury, disease or its symptoms;
 - In accordance with generally accepted standards of medical practice;
 - Clinically appropriate in terms of type, frequency, extent, site and duration;
 - Not primarily for the convenience of the patient, physician or other health professional.
 - Not more costly than an alternative service(s), medication(s) or supply(ies) that is at least as likely to produce equivalent therapeutic or diagnostic results with the same safety profile as to the prevention, evaluation, diagnosis or treatment of the member's sickness, injury, condition, disease or its symptoms; and
 - Rendered in the least intensive setting that is appropriate for the delivery of the services, supplies or medications. Where applicable, the Medical Director or Review Organization may compare the cost-effectiveness of alternative services, supplies, medications, or settings when determining least intensive setting.
8. Pharmacy: A duly licensed Pharmacy that dispenses Prescription Drug Products in a retail setting or via home delivery. A home delivery Pharmacy is a Pharmacy that primarily provides Prescription Drug Products through mail order.
9. Utilization Management ("UM") requirements: mean methods by which a health plan or Pharmacy Benefit Management (PBM) manage coverage for drugs. UM requirements may include, but are not limited to, Step Therapy, Prior Authorization, Quantity Limits, and Age Limits.
 - Step Therapy ("ST"): means a form of UM that requires, as a condition of coverage for a drug product, a customer to try an alternative drug product or demonstrate contraindication, failure or intolerance of such product for the customer's medical condition.
 - Prior Authorization ("PA"): means a form of UM that requires, as a condition of coverage, a customer or the customer's prescriber to obtain prior approval from Cigna Healthcare, based on coverage criteria set forth in a coverage policy.
 - Quantity Limits ("QL"): means a form of UM that limits the amount of medication over a defined period of time for which a plan provides coverage.

Supporting Documents:

Document/Policy Name	Description
Connect Bronze 6500 Indiv Med Deductible Plan Booklet	Plan specific document that outlines the details of a health insurance plan, including plan and benefit information, claim review procedures, and participation rights. The plan booklet provides comprehensive information about what the plan covers, how it is administered, and the procedures for reviewing claims. It is intended to help members understand their rights and responsibilities under the plan.
Virginia IFP MED SURG 01012025 By Formulary	This document reflects the M/S formularies including which drugs require prior authorization.
Virginia IFP MH SUD 01012025 By Formulary	This document reflects the MH/SUD formularies including which drugs require prior authorization.
PH-THP-23 Cigna Healthcare Value Assessment Committee Description and Annual Membership Certification	This document defines the charter of the Cigna Healthcare Value Assessment Committee
PSC 012 Verification of Pharmacists Licensure Policy	Pharmacists perform utilization review, prescription verification, clinical oversight and other duties based on the department in which they are responsible for performing tasks for Cigna's Coverage Review Operations. Additionally, certified pharmacy technicians may perform other, non-clinical duties. This document outlines the procedure followed by management to verify the licensure of Pharmacists and certifications of pharmacy technicians (if applicable) employed by Cigna's Commercial Coverage Review department and the responsibilities of Pharmacists and certified pharmacy technicians regarding their licensure and /or certifications.
OPS 53 Internal Credentialing for the National Appeals Organization	Establish a consistent process to verify the current licensure and credentials of Internal physicians and practitioners.

Services Subject to the NQTL

Cigna requires prior authorization, step therapy, or quantity limits for certain prescription drugs to ensure the prescribed drugs are medically necessary to treat the enrollee's condition. Cigna uses the same medical necessity standard when reviewing coverage for both medical/surgical and MH/SUD drugs.

Cigna's prior authorization, step therapy, or quantity limit requirements were developed without regard to whether the prescription drugs are prescribed to treat a M/S or a MH/SUD condition.

Step 2: Identification and definition of the factors and evidentiary standards used to design or apply the NQTL.

See [45 CFR 146.137\(c\)\(2\)](#). Step 2 must include, with respect to every factor considered or relied upon to design or apply the NQTL to MH or SUD benefits and medical/surgical benefits, the following:

- (i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which MH or SUD and which medical/surgical benefits are subject to the NQTL; and
- (ii) A definition of each factor, including:
 - (A) A detailed description of the factor;
 - (B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (i) above; and
 - (C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective.

See also [FAQ 45](#) guidance. This FAQ guidance stipulates that a sufficient analysis includes:

- (Q2, #3) Identification of any factors, evidentiary standards or sources, or strategies or processes considered in the design or application of the NQTL and in determining which benefits, including both MH/SUD benefits and medical/surgical benefits, are subject to the NQTL. Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.
- (Q2, #4) To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

This FAQ guidance stipulates what plans and issuers should avoid:

- (Q3, #5) Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Issuer Response:

The factors considered in deciding to apply a prior authorization requirement, including potentially a quantity limit, to a drug primarily include the (1) risk of adverse safety issues, (2) specialty drug status, or (3) risk of inappropriate (i.e., wasteful) utilization, and (4) clinical safety and efficacy. The presence of any one factor as defined below will warrant application of prior authorization.

Step therapy requirements are developed without regard to whether the prescription drugs are prescribed to treat a M/S condition or a MH/SUD condition. When deciding whether to apply a step therapy NQTL to a prescription drug, the formulary committee considers the following factors: whether the drug in question is (1) available; (2) has lower net cost therapeutic alternatives and the formulary committee evaluates that enrollees would not generally switch therapy from the

drug in question to a preferred alternative drug, or, if new to therapy, may not start therapy on the preferred drug(s), absent application of the step therapy requirement; (3) whether, as a clinical matter the Pharmacy & Therapeutics Committee (“P&T Committee”) clinical findings prohibit application of step therapy; (4) the projected cost savings associated with application of the step therapy requirement; and (5) safety and efficacy.

The Pharmacy and Therapeutics (“P&T”) Committee participants include independent, actively practicing physicians and clinical pharmacists from across the U.S. The committee meets six times per year to examine the safety and efficacy of new drugs and biologics as well as clinical updates to drugs and biologics previously reviewed by the committee. The P&T Committee is designed to ensure an unbiased clinical perspective for the formulary evaluation process from practicing physicians and pharmacists reflecting a variety of practice specialties.

The Cigna Healthcare Value Assessment Committee (“HVAC”) is a chartered committee comprised of voting and non-voting representatives across various business units such as clinical, medical, and business leadership that is duly authorized by Cigna Healthcare to make decision regarding coverage treatment of Drug Products based on clinical finding provided by the P&T Committee, including, but not limited to, decisions regarding tier placement and application of utilization management

The factors considered in deciding to apply quantity limits include (1) safety and efficacy and (2) risk of adverse safety issues.

Factors	Sources for Each Factor
Prior Authorization: The following factors are considered when deciding whether to apply prior authorization to a drug and any one of the factors listed below would warrant the application of prior authorization: 1. Risk of adverse safety issues: Prior authorizations are put in place to ensure appropriate diagnosis for prescribing align with FDA labeling, maximum dosing recommendations (quantity limitations), P&T guidance. The risk of adverse safety issues is a factor for applying quantity limits and utilized to ensure appropriate diagnosis for prescribing medications align with FDA labeling, maximum dosing recommendations (quantity limitations), P&T guidance. Drugs that have a quantity limit applied under the risk of adverse safety issue are drugs that potentially have a high risk of	Prior Authorization: 1. Risk of adverse safety issues: Sources for adverse safety issues are NIH, Cigna policies, Special Investigations Unit, Fraud Waste and Abuse (FWA) reports which monitor claim trends and extensive compounded products, FWA trend alerts for formulary issues such as off label use and removal of egregiously priced drugs. Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/ Benefits of Prior Authorizations - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10391030/ Why Choose Us as Your Healthcare Partner Cigna Healthcare https://www.cigna.com/employers/why-cigna/#controlling-costs m-24-rx-all-967425-utilization-management-flyer.pdf (cigna.com) https://www.cigna.com/static/www-cigna-com/docs/ifp/m-24-rx-all-967425-utilization-management-flyer.pdf Medication Therapy Management Program Cigna Healthcare https://www.cigna.com/medicare/member-resources/medication-therapy-management

adverse effects. These drugs are identified as one where exceeding its maximum FDA-recommended dose may cause material patient harm. 2. Specialty drug status: Specialty drugs are FDA-approved high-cost medications that treat rare diseases, complex, and chronic health conditions like rheumatoid arthritis, multiple sclerosis, and cancer. The drugs themselves may require special handling and storage (e.g., refrigeration), preparation, and patients who use them may need to work closely with doctors, pharmacists, and other health care providers who can monitor the patient's progress. In some instances, depending on state law, a specialty pharmacy fills specialty drugs, and the specialty drugs may be provided via exclusive specialty home delivery. Specialty medications are typically taken orally, injected, infused, or inhaled. Specialty drugs may also be administered at home. 3. Inappropriate utilization: Utilization management such as step therapy, prior authorization and quantity limits are in place as a way to decrease inappropriate utilization and to ensure therapeutic appropriateness. Inappropriate medication prescribing is associated with adverse health outcomes and increased health care costs. Inappropriate utilization means inappropriate treatment or care based on medically accepted standards relating to both the level and the quality of health care and health care services provided to a patient. Inappropriate utilization can also encompass the prescribing of a drug with a greater potential risk rather than benefit in terms of dosing, treatment, and adverse drug reactions. Other examples of inappropriate utilization could include: the prescribing of a drug that does not have an FDA approved indication,	Cigna Healthcare Coverage Policies Cigna Healthcare https://www.cigna.com/legal/members/member-rights-and-responsibilities/cigna-health-care-policies 2. Specialty drug status: Sources for specialty drug status are as follows: Specialty Pharmacy Management for Employers Cigna Healthcare https://www.cigna.com/employers/pharmacy/specialty/How Accredo's specialty pharmacists support patients with highly complex conditions Evernorth https://www.evernorth.com/articles/how-accredos-specialty-pharmacists-support-patients-highly-complex-conditions What Makes a Drug Special? Defining Specialty Medications (powerpak.com) 3. Inappropriate utilization: Sources utilized for inappropriate utilization are as follows: Inappropriate medications and physical function: a systematic review - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8287273/ Medication Therapy Management Program Cigna Healthcare https://www.cigna.com/medicare/member-resources/medication- therapy-management m-24-rx-all-967425-utilization-management-flyer.pdf (cigna.com) https://www.cigna.com/static/www-cigna-com/docs/ifp/m-24-rx-all- 967425-utilization-management-flyer.pdf Cigna Healthcare Coverage Policies Cigna Healthcare – medical https://www.cigna.com/legal/members/member-rights-and- responsibilities/cigna-health-care-policies#utilization-management 4. Clinical safety and efficacy: The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed concepts for prior authorization practices by MCOs Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/ 5. Clinical guidelines and standards of the P&T committee The sources for clinical guidelines are clinical findings case studies, peer-reviewed journals, Risk Evaluation and Mitigation Strategy (REMS), primary medical literature; published data from clinical trials; clinical practice guidelines and FDA product information. Drug compendium (list of drugs and biologicals approved by the FDA), internal fraud, waste and abuse reports from Cigna's Special Investigation Unit, and utilization trends (e.g., evidence of potential inappropriate use).The sources Healthcare Value Assessment Committee (HVAC) relies are including but not limited to expert internal and external clinical evidence documentation,
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inappropriately prescribing a drug for an indication that a patient does not have, or any other methods that may incur fraud, waste, and abuse. Cigna has utilization management tools in place, such as step therapy, prior authorization and quantity limits to promote patient safety, decrease inappropriate utilization and to promote appropriate therapeutic utilization. Inappropriate utilization, including inappropriate medication prescribing, is associated with adverse health and safety outcomes and increased health care costs. 4. Clinical safety and efficacy: Clinical safety and efficacy are defined by a drug/class that is identified as one with high waste, abuse or overuse potential. Prior authorizations (“PA”) are put in place to ensure the patient is given the correct drug, for the appropriate diagnosis, at the appropriate dose to achieve a positive clinical outcome. 5. Clinical guidelines and standards of the P&T committee: Clinical guidance is the parameters determined by the P&T committee. Guidelines summarize the current medical knowledge, weigh the benefits and harms of diagnostic procedures and treatments, and give specific recommendations based on this information. The guidelines also provide information about the scientific evidence supporting those recommendations. Clinical practice guidelines are updated regularly. Healthcare Value Assessment Committee (HVAC) is responsible for taking recommendations and findings from the P&T Committee and translating them into actionable coverage policy and formulary decisions.	information provided from pharmaceutical manufacturers, the FDA, and information gleaned from external clinical bodies and industry groups
Step Therapy: 1. Availability: The availability of medical or pharmacy medications (products) depends upon two market conditions (1) the market	Step Therapy: 1. Availability: Sources for availability are FDA drug shortage tracker, internal drug shortage tracker which tracks drugs ad hoc, and the American Society Hospital Pharmacy drug shortage list.

availability for drug manufacturers to manufacture ample amount of product to be distributed to wholesalers for patient consumption or patient utilization and (2) market trends, for example, for example, GLP 1 drugs and ADHD drugs demand has increased, manufacturer raw materials, manufacturing practices, manufacturing processes, and published FDA drug shortages. Product availability means the ability of manufacturers to meet demand; lack of product availability means demand exceeds supply. Market availability means the number of manufacturers and buyers who are willing and able to participate in the market. Market means any entity licensed to dispense medication. The geographic market means national, publicly available sources. Market demand means the pharmacy supply and demand. The pharmaceutical supply chain involves the process of sourcing raw materials, manufacturing, distributing and delivering/dispensing medication to patients. 2. Lower net cost therapeutic: An appropriate generic, or a therapeutic equivalent brand name in the same class may be preferred over a more expensive brand name product to determine equivalent therapeutic results by utilizing a lower net cost therapeutic product. A generic is a drug created the same as brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Therapeutic equivalents are approved drug products for which bioequivalence has been demonstrated and are expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. 3. Clinical guidelines and standards of the	2. Lower net cost therapeutic: Sources for lower net cost therapeutic: FDA Generic Drugs: Question and Answers (2021) FDA Orange Book Center for Drug Evaluation and Research with Therapeutic Equivalence Evaluations January 25, 2024 P&T Guidance Projected cost savings and the expected utilization rate of the preferred drug(s) absent the step therapy requirement, which also includes an analysis of drug claims utilization information and net drug cost information. The primary source for drug claims utilization and net drug cost is Cigna's internal pharmaceutical economic data analysis. State mandates, pharmaceutical rebates are also sources under consideration whereby Cigna negotiated a contract with the manufacturer whom only provides non-generic; therefore, this contracted rebate rate decreased the overall net cost when compared to other brand name in same category - - this is only for drugs that have no generics, single source brands. To manage drug costs Cigna utilizes the following external industry standard sources: Academy of Managed Care Pharmacy Managing Drug Costs, Academy of Managed Care Pharmacy Managing Pharmacy Tools National Institutes of Health, Focus on Lowest Net Cost Drug Reduces Costs for Patients, Plan Sponsor. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106542/ 3. Clinical guidelines and standards of the P&T and HVAC committees: The sources for clinical guidelines are clinical findings case studies, peer-reviewed journals, Risk Evaluation and Mitigation Strategy (REMS), primary medical literature; published data from clinical trials; clinical practice guidelines and FDA product information. The sources Healthcare Value Assessment Committee (HVAC) relies on are including, but not limited to, expert internal and external clinical evidence documentation, information provided by pharmaceutical manufacturers, the FDA, and information gleaned from external clinical bodies and industry groups 4. Projected cost savings: Sources for projected cost savings include internal pharmacy economics. External Intellectual Product Development Analytics are used for drug forecasting, including a market basket. 5. Clinical safety and efficacy: Sources for clinical safety and efficacy under Prior Authorization are as follows: The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed concepts for prior authorization practices by MCOs
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P&T and HVAC committees: Clinical guidance is the parameters determined by the P&T committee. Guidelines summarize current medical knowledge, weigh the benefits and harms of diagnostic procedures and treatments, and give specific recommendations based on this information. The guidelines also provide information about the scientific evidence supporting those recommendations. Clinical practice guidelines are updated regularly. Healthcare Value Assessment Committee (HVAC) is responsible for taking recommendations and findings from the P&T Committee and translating them into actionable coverage policy and formulary decisions. 4. Projected cost savings: Projected cost savings is based on formulary modeling to determine net cost of the target drug and the formulary alternatives. 5. Clinical Safety and Efficacy: Clinical safety and efficacy are defined by a drug/class that is identified as one with high waste, abuse or overuse potential. Prior authorizations ("PA") are put in place to ensure the patient is given the correct drug, for the appropriate diagnosis, at the appropriate dose to achieve a positive clinical outcome.	Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/
Quantity Limits: While Quantity Limits could be listed within Step Therapy and Prior Authorization, Cigna has listed this limitation separately, although the factor definitions and sources remain the same as what is listed in PA and ST. The following factors are considered when deciding whether to implement a quantity limit: 1. Clinical safety and efficacy: Clinical safety and efficacy are defined by a drug/class that is identified as one with	Quantity Limits: 1. Clinical safety and efficacy Sources for clinical safety and efficacy under Prior Authorization is as follows: The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee developed concepts for prior authorization practices by MCOs Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/ 2. Risk of adverse safety issues: Sources for adverse safety issues are NIH, Cigna policies, Special Investigations Unit, Fraud Waste and Abuse (FWA)

high waste, abuse or overuse potential. Prior authorizations (“PA”) are put in place to ensure the patient is given the correct drug, for the appropriate diagnosis, at the appropriate dose to achieve a positive clinical outcome. 2. Risk of adverse safety issues: Prior authorizations are put in place to ensure appropriate diagnosis for prescribing align with FDA labeling, maximum dosing recommendations (quantity limitations), P&T guidance. The risk of adverse safety issues is a factor for applying quantity limits and utilized to ensure appropriate diagnosis for prescribing medications align with FDA labeling, maximum dosing recommendations (quantity limitations), P&T guidance. Drugs that have a quantity limit applied under the risk of adverse safety issue are drugs that potentially have a high risk of adverse effects. These drugs are identified as one where exceeding its maximum FDA-recommended dose may cause material patient harm.	reports which monitor claim trends and extensive compounded products, FWA trend alerts for formulary issues such as off label use and removal of egregiously priced drugs. Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/ Benefits of Prior Authorizations - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10391030/ Why Choose Us as Your Healthcare Partner Cigna Healthcare https://www.cigna.com/employers/why-cigna/#controlling-costs m-24-rx-all-967425-utilization-management-flyer.pdf (cigna.com) https://www.cigna.com/static/www-cigna-com/docs/ifp/m-24-rx-all-967425-utilization-management-flyer.pdf Medication Therapy Management Program Cigna Healthcare https://www.cigna.com/medicare/member-resources/medication-therapy-management Cigna Healthcare Coverage Policies Cigna Healthcare https://www.cigna.com/legal/members/member-rights-and-responsibilities/cigna-health-care-policies
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In the making and determination of Pharmacy Services NQTL there were no additional factors considered and rejected. The factor that is given more weight than another is patient safety. Safety data comes from the product’s package insert, which sites clinical studies used in the approval process. For instance, Cigna places a quantity limit on a drug if there is a risk of adverse effects and if taken over the recommended daily dosage.

When all of the evidentiary standards defining such factors are met, then the formulary committee applies the step therapy requirement to a drug. Notably, there are instances where an MH/SUD drug may not be subject to step therapy even if all of the evidentiary standards for application of the NQTL are met. Specifically, the plan does not apply step therapy requirements to any drugs used to treat opioid use disorder or alcohol use disorder, even though in some cases it would be warranted under the factors and standards that inform application of step therapy. This less stringent application of step therapy to MH/SUD drugs is, of course, permitted by the parity NQTL requirement, which only prohibits application of step therapy to MH/SUD drugs that is more stringent as compared to application of the same to M/S drugs.

Factor	Evidentiary Standards and Applicable Thresholds	Source(s) for Each Evidentiary Standard
Prior Authorization:	Prior Authorization:	Prior Authorization:

1. Risk of adverse safety issues 2. Specialty drug status 3. Inappropriate utilization 4. Clinical safety and efficacy 5. Clinical guidelines and standards	1. Risk adverse safety issue: The evidentiary standard used to define whether a drug poses an adverse safety issue is the availability of clinical evidence, including, without limitation, FDA labeling, clinical guidelines or clinical literature. This evidence is reviewed in its totality by relevant experts, though certain attributes such as the status of a drug as a controlled substance will, if present, result in application or a prior authorization requirement on the basis of potentially serious adverse safety impacts to enrollees. Controlled substances subject to prior authorization or a quantity limit include ADHD stimulants, which are MH/SUD benefits, and other controlled substances used to treat M/S conditions like opioids for pain management. For other drugs, the FDA’s product label generally indicates whether a serious adverse safety risk exists for a drug, though sometimes, such as with opioids, other widely accepted clinical guidelines such as CDC guidance may also dictate whether a prior authorization requirement will apply. 2. Specialty drug status: The evidentiary standard used to define whether a drug is a specialty drug, and thus is subject to prior authorization, is the presence of one more of the following characteristics based on an assessment of available clinical evidence like FDA product labeling, clinical literature and guidelines: the requirement for frequent dosing adjustments and intensive clinical monitoring to decrease the potential for drug toxicity and increase the probability for beneficial treatment outcomes; the need for intensive patient training and compliance assistance to facilitate therapeutic goals; limited or exclusive specialty pharmacy distribution (if a drug is only available through limited specialty pharmacy distribution it is considered specialty, even if it doesn’t have other specialty drug characteristics); or specialized product handling and/or administration requirements. Frequent dosing is monitored by the provider and dosing is determined by the drug manufacturer and approved by the FDA. Dosing is adjusted per patient and decided by the provider. 3. Inappropriate utilization: The evidentiary standard used to define whether a drug poses a risk of inappropriate or wasteful utilization such that a quantity limit or other prior authorization requirement should apply are the CMS definitions of “waste” or “misuse.” More specifically, if the	1. Risk of adverse safety issues FDA labeling, clinical guidelines or clinical literature 2. Specialty drug status First DataBank and Medispan drug databases; Accredo, specialty drug indicator. 3. Inappropriate utilization clinical literature or guidelines, or claims trend data internal or external from FirstData bank 4. Clinical safety and efficacy: Sources for clinical safety and efficacy are manufacturer reports, clinical trials and studies, FDA labeling, clinical literature, NIH, FDA, and AMCP. 5. Clinical guidelines and standards: Sources for clinical guidelines and standard are clinical data and manufacturer FDA approved clinical labeling/medication package inserts.
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	formulary committee identifies through external publications like clinical literature or guidelines, or claims trend data internal or external from First Databank, that a particular drug(s) in a class may be, or are, being routinely prescribed in amounts exceeding FDA-established dosage recommendations or for otherwise clinically inappropriate uses then it may approve application of prior authorization, such as quantity limits, to those drugs. This particular factor was present for the range of drugs, including MH/SUD drugs like anti-depressants and anti-psychotics and M/S drugs including asthma, antiemetics, cardiovascular/hypertension, anaphylactic, androgenic growth hormones, diabetes GLP-1, and acne drugs. There is a comparatively higher incidence of M/S drugs for which these factors are not present, including over-the-counter drugs and many prescription drugs considered to be M/S benefits. 4. Clinical safety and efficacy: The evidentiary standard for the factor regarding clinical safety and efficacy is manufacturer safety reports, clinical trials, and FDA labeling. Clinical organizations such as NIH, FDA, and AMCP who establish guidance to use utilization management criteria to optimize patient outcomes and reduce waste, error, and unnecessary drug use to ensure the safety and clinical appropriateness of medication therapy management. The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed specific concepts for effective prior authorization practices by MCOs. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents. Sources for clinical safety and efficacy are manufacturer reports, clinical trials and studies, FDA labeling, clinical literature, NIH, FDA, and AMCP. 5. Clinical guidelines and standards: The evidentiary standard for clinical guidelines and standards is established clinical organizations such as NIH, FDA, and AMCP who set forth clinical guidance. Also, clinical data as well as the manufacturer FDA approved clinical labeling/medication package inserts are utilized to ensure clinical guidelines and	
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	standards are followed.	
Step Therapy Evidentiary Standards: The evidentiary standard for the factors regarding availability, lower net cost therapeutic alternatives, projected cost savings (expected utilization rate) of the preferred drug(s) is whether an analysis of claims information and available information regarding availability of therapeutic alternatives to the drug in question dictates that there is/are drug(s) available that the formulary committee could prefer over the drug in question through application of a step therapy Step Therapy: 1. Availability 2. Lower net cost therapeutic 3. Clinical guidelines and standards 4. Projected cost savings 5. Clinical safety and efficacy	Step Therapy: 1. Availability: The evidentiary standard for the availability whether the following show the drug is available: • An analysis of claims and service center data • FDA and industry publications such as the FDA drug shortages database • Manufacturer websites show the drug is available If the drug is available, then the drug may be addressed by the formulary committee. 2. Lower net cost therapeutic alternatives: The evidentiary standard for lower net cost therapeutic alternatives is whether the alternative drug is a therapeutic alternative, which can be determined by utilizing the following sources: • Pharmacy economics data • The FDA Orange Book Data Files to determine if something is an interchangeable generic • Intellectual Product Development (IPD) analytics. IPD analytics is used to determine if the drug is an alternative on the formulary. • Formulary modeling is used to determine net cost of the target drug and the formulary alternatives. There is no dollar threshold when utilizing the lowest net cost methodology for formulary development, the analysis is conducted of a drug when compared to other drugs used for the same indication. Cigna utilizes the lowest net cost methodology for formulary development while giving more weight to safety and efficacy. A formulary model is drug class specific and developed in collaboration with the pharmacy economics area. The following are examples of data points that may or may not be included in the formulary model, depending which drug class is being modeled: • market basket defining what therapeutically equivalent drugs are being reviewed • pharmacy claims data • drug cost information (AWP) • current formulary coverage • current market share • drug specific rebate information • shift assumptions	Step Therapy: 1. Availability: The sources for availability are an analysis of drug claims utilization information and/or net drug cost information, FDA, and manufacturer websites 2. Lower net cost therapeutic: Sources for lower net cost therapeutic are: • Pharmacy economics data • The FDA Orange Book Data Files to determine if something is an interchangeable generic • Intellectual Product Development (IPD) analytics. IPD analytics is used to determine if the drug is an alternative on the formulary. • Formulary modeling is used to determine net cost of the target drug and the formulary alternatives. 3. Clinical guidelines and standards: The sources for the factor clinical guidelines and standards include: Sources to identify a small sub-population included the NIH, NEJM, and The Cigna Group Health Equity webpage. • Health Equity The Cigna Group, health-equity.pdf

	• drug discounts • risk adjustment • drug information (brand/generic, base/specialty) • affordability projection period • historic member months Once the formulary model is complete, the output is reviewed to determine if it makes sense from a financial perspective to implement the proposed formulary changes. 3. Clinical guidelines and standards: The evidentiary standard for the factor regarding whether it is clinically permissible for the plan to require use of one drug over another as a condition of coverage is whether the P&T Committee has designated a drug as therapeutically interchangeable with its therapeutic alternatives. That is, if an assessment of available clinical information reveals that enrollees will generally experience similar outcomes in terms of safety and efficacy if using any of the drugs being assessed, then the formulary committee may approve application of a step therapy requirement to one or more of the drugs in the therapeutic class or grouping. More specifically, if a drug within a therapeutic class possesses an equivalent, or greater, clinical designation than an alternative drug(s), then that drug may be preferred through a step therapy requirement applied to the other drug(s) in the class. The P&T Committee assigns one of several clinical designations to a drug based on the drug's safety/efficacy and place in therapy: Access, Include, Optional, or Exclude. These designations provide the clinical basis and evidence for placement on the drug list whether, from a clinical perspective a drug must be covered on the formulary, or, alternatively, may, but is not required to be, covered on the formulary, and whether a drug may be covered more favorably than therapeutically alternative drugs. A drug designated "Include" or "Access" must be covered to the extent medically necessary, and alternative drugs may not be preferred over it through application of tier placement or step therapy. A drug designated "Optional" may or may not be covered on the formulary and may be subject to a step therapy protocol that requires the use of alternative drugs.	(cigna.com) • https://www.cigna.com/static/www-cigna-com/docs/health-equity.pdf • Applying a Subpopulation Lens to Population Health NEJM • https://www.nejm.org/doi/full/10.1056/NEJMp2113023 • An approach to addressing subpopulation considerations in systematic reviews: the experience of reviewers supporting the U.S. Preventive Services Task Force - PMC (nih.gov) • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5335853/ The sources for determining that the drug is similar in terms of safety and efficacy to other currently available drug alternatives include: • The FDA's Drug Review Process, NIH, and AAFP. • Ensuring Drugs Are Safe and Effective FDA, Overview of methods for comparing the efficacies of drugs in the absence of head-to-head clinical trial data - PMC • (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3895352/ • Methods - Criteria for
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	These formulary placement designations are more specifically defined as follows, and are subject to any overriding plan exclusions such as exclusions of over-the-counter drugs or prescription drugs with over-the-counter alternatives: Include: A drug may be given an include designation if it meets at least one of the clinical bases enumerated below and is anticipated, or validated via claims data, to treat relatively large patient population (i.e., greater than 1 in 50,000). The clinical basis includes: ○ It has a unique indication for use addressing a clinically significant unmet treatment need; ○ Its efficacy is superior to that of existing therapy alternatives; ○ Its safety profile is superior to that of existing therapy alternatives, it has a unique place in therapy; and/or ○ It treats medical condition(s) that necessitate individualized therapy and for which there are multiple treatment options. Include drugs must be placed on a tier of the applicable formulary by the Healthcare Value Assessment Committee but may not be disadvantaged relative to other drugs in a drug grouping, as defined by the P&T Committee, with a less favorable clinical designation. A drug grouping is a list of drugs that generally possess the same mechanism of action and a similar place in therapy. Definitions: • A unique indication for use addressing a clinically significant unmet treatment need means a drug that can treat an indication for which there is no other current therapy. The identification of a particular drug is based on clinical trials, FDA guidance and unique offering in the market. • Efficacy is superior means that a drug's clinical outcomes surpass other drugs for the same indications. Efficacy is based on clinical studies involved in a drug's approval which is admitted by the FDA, established guidelines from professional medical societies, and the P&T Committee's clinical expertise, experience and judgement. Access: A drug may be given an access designation if it meets at least one of the clinical basis enumerated below AND the drug is either anticipated or validated via claims data at the time the P&T Committee renders a designation on the	Distinguishing Effectiveness From Efficacy Trials in Systematic Reviews - NCBI Bookshelf (nih.gov) https://www.ncbi.nlm.nih.gov/books/NBK44028/ • Evaluating the Safety and Effectiveness of New Drugs AAFP https://www.aafp.org/pubs/afp/issues/2010/0701/p53.html The sources for the factor regarding the P&T's clinical findings that govern whether use of one drug may be required over another as a condition of coverage are an assessment of FDA-product labeling and available clinical guidelines or literature published by the government, professional societies and/or medical publications. 4. Projected cost savings: Sources for projected cost savings include internal pharmacy economics and External Intellectual Product Development Analytics which is used for drug forecasting, including a market basket. 5. Clinical safety and efficacy: Sources for clinical safety and efficacy are manufacturer reports, clinical trials and studies, FDA labeling, clinical literature, NIH, FDA, and AMCP.
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	drug, to treat a relatively small sub-population. The clinical basis include: ○ It has a unique indication for use addressing a clinically significant unmet treatment need; ○ Its efficacy is superior to that of existing therapy alternatives; ○ Its safety profile is superior to that of existing therapy alternatives; ○ It has a unique place in therapy; and/or ○ It treats medical condition(s) that necessitate individualized therapy and for which there are multiple treatment options Access drugs are forwarded to the Healthcare Value Assessment Committee for further analysis of whether the drug should be covered on the applicable formulary and, if covered on the formulary, on which tier. The Healthcare Value Assessment Committee may either place the drug on the applicable formulary or designate the drug as non-formulary. If the Healthcare Value Assessment Committee does not place the drug on the formulary, the P&T Committee shall establish formulary exception clinical criteria. Definitions: • A small sub population is defined as a subdivision of a population, with common, distinguishing characteristics. Populations are composed of myriad subpopulations, each with its own health profile. A key subpopulation must be considered in efforts to enhance population health is a group whose characteristics pose distinct opportunities and challenges. Sources to identify a small sub-population included the NIH, NEJM, and The Cigna Group Health Equity webpage Health Equity The Cigna Group, health-equity.pdf (cigna.com) https://www.cigna.com/static/www-cigna-com/docs/health-equity.pdf Applying a Subpopulation Lens to Population Health NEJM https://www.nejm.org/doi/full/10.1056/NEJMp2113023 An approach to addressing subpopulation considerations in systematic reviews: the experience of reviewers supporting the U.S. Preventive Services Task Force - PMC (nih.gov)	
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	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5335853/ • Safety profile is superior means that the rate or instances of adverse reactions is far less than other drugs used to treat the same indication. Safety profile is based on clinical studies involved in a drugs approval, which is admitted by the FDA • Unique place in therapy means that other drug or product is used to treat a specific indication. The identification of a particular drug is based on clinical trials, FDA guidance and unique offering in the market • Necessitate individualized therapy and for which there are multiple treatment options means that therapy is unique for an individual based on clinician evaluation and there are different therapies that could be used for such treatment. FDA guidance and clinical studies are sources for determining different therapies. Optional: A drug may be given an optional designation if a significant proportion of its use is similar in terms of safety and efficacy to other currently available drug alternatives. In certain instances, a drug designated as optional may have a unique use in a small subset of patients in relation to the overall use of the drug. The P&T Committee shall establish formulary exceptions to account for cases where the optional drug may have a unique use in a relatively small subset of patients. Optional drugs are forwarded to the Value Assessment Committee for further analysis of whether the drug should be covered on the applicable formulary and, if covered on the formulary, on which tier. The Healthcare Value Assessment Committee may either place the drug on the formulary or designate the drug as non-formulary. If the drug is not placed on the formulary, the P&T Committee shall establish formulary exception clinical criteria. The sources for determining that the drug is similar in terms of safety and efficacy to other currently available drug alternatives include: The FDA’s Drug Review Process, NIH, and AAFP. Ensuring Drugs Are Safe and Effective FDA, Overview of methods for comparing the efficacies of drugs in the absence of head-to-head clinical trial data - PMC (nih.gov) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3895352/	
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	Methods - Criteria for Distinguishing Effectiveness From Efficacy Trials in Systematic Reviews - NCBI Bookshelf (nih.gov) https://www.ncbi.nlm.nih.gov/books/NBK44028/ Evaluating the Safety and Effectiveness of New Drugs AAFP https://www.aafp.org/pubs/afp/issues/2010/0701/p53.html Exclude: Drugs may be given an exclude designation for one or more of the following clinical reasons: efficacy inferior to that of existing therapy alternatives, a safety profile inferior to that of existing therapy alternatives, and/or insufficient data to evaluate the drug. Drugs recalled from the market for safety reasons are automatically designated as “Exclude” drugs, pending further P&T Committee review. The sources for the factor regarding the P&T’s clinical findings that govern whether use of one drug may be required over another as a condition of coverage are an assessment of FDA-product labeling and available clinical guidelines or literature published by the government, professional societies and/or medical publications. 4. Projected cost savings: The evidentiary standard for the factor regarding the projected cost savings associated with application of a step therapy requirement is whether application of the step therapy requirement projects to result in measurable cost savings based on an assessment of projected claims expenditures for the drug without application of the step therapy requirement as compared to projected claims expenditures relating to the drug’s utilization, and administration of the step therapy requirement, if subject to the step therapy requirement. If the projected expenditures relating to the drug’s utilization, if subject to the step therapy requirement are measurably lower as assessed across the national book-of-business, that is, produce measurable savings, relative to the baseline scenario without application of the step therapy requirement, then the factor’s evidentiary standard is met. 5. Clinical safety and efficacy: The evidentiary standard for the factor regarding clinical safety and efficacy is manufacturer safety reports, clinical trials, and FDA labeling. Clinical organizations such as NIH, FDA, and AMCP who	
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	establish guidance to use utilization management criteria to optimize patient outcomes and reduce waste, error, and unnecessary drug use to ensure the safety and clinical appropriateness of medication therapy management. The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed specific concepts for effective prior authorization practices by MCOs. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents. Sources for clinical safety and efficacy are manufacturer reports, clinical trials and studies, FDA labeling, clinical literature, NIH, FDA, and AMCP.	
Quantity Limits: 1. Risk of adverse safety issues 2. Clinical safety and efficacy	Quantity Limits: Quantity limits, a form of prior authorization whereby an enrollee must obtain authorization to receive coverage if a prescription exceeds a certain amount/dosage of a drug, are applied to certain MH/SUD and M/S drugs. Indeed, MH/SUD drugs are available on the market in multiple dosage forms, and use of multiple lower dosages, or more pills/films of a lower dosage, would be costlier to the plans, such that applying a limit on the number of pills/films that will be covered without demonstrated medical necessity is appropriate. Quantity limits are applied to address safety, not applied relative to cost considerations. 1. Clinical Safety and Efficacy: The evidentiary standard for the factor regarding clinical safety and efficacy is manufacturer safety reports, clinical trials, and FDA labeling. Clinical organizations such as NIH, FDA, and AMCP who establish guidance to use utilization management criteria to optimize patient outcomes and reduce waste, error, and unnecessary drug use to ensure the safety and clinical appropriateness of medication therapy management. The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed specific concepts for effective prior authorization practices by MCOs. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices,	Quantity Limits: 1. Clinical safety and efficacy: Sources for clinical safety and efficacy are manufacturer reports, clinical trials and studies, FDA labeling, clinical literature, NIH, FDA, and AMCP. 2. Risk of adverse safety issues FDA labeling, clinical guidelines or clinical literature

	and other therapeutic agents. Sources for clinical safety and efficacy are manufacturer reports, clinical trials and studies, FDA labeling, clinical literature, NIH, FDA, and AMCP. 2. Risk of adverse safety issues: With respect to whether prior authorization (including a quantity limit) is applied to a drug covered under the prescription drug classification, the evidentiary standard used to define whether a drug poses an adverse safety issue is clinical evidence, including, without limitation, FDA labeling, clinical guidelines or clinical literature. This evidence is reviewed in its totality by relevant experts, though certain attributes such as the status of a drug as a controlled substance will, if present, result in application of a prior authorization requirement on the basis of potentially serious adverse safety impacts to enrollees. Controlled substances subject to prior authorization or a quantity limit include ADHD stimulants, which are MH/SUD benefits, and other controlled substances used to treat M/S conditions like opioids for pain management. For other drugs, the FDA's product label generally indicates whether a serious adverse safety risk exists for a drug, though sometimes, such as with opioids, other widely accepted clinical guidelines such as CDC guidance may also dictate whether a prior authorization requirement will apply.	
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Step 3: Description of how factors are used in the design and application of the NQTL.

See [45 CFR 146.137\(c\)\(3\)](#). Step 3 must include the following: A description of how each factor identified and defined under Step 2 is used in the design or application of the NQTL to MH and SUD and medical/surgical benefits in a classification, including:

- (1) A detailed explanation of how each factor identified and defined in Step 2 is used to determine which MH or SUD benefits and which medical/surgical benefits are subject to the NQTL;
- (2) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and

- how MH or SUD or medical/surgical benefits are subject to the NQTL;
- (3) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualification of each decision maker;
 - (4) If more than one factor is identified and defined in Step 2, an explanation of:
 - (A) How all of the factors relate to each other;
 - (B) The order in which all of the factors are applied, including when they are applied;
 - (C) Whether and how any factors are given more weight than others; and
 - (D) The reasons for the ordering or weighting of the factors.
 - (5) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which evidentiary standards was derived), such as how the factor is used differently to apply the NQTL to MH or SUD benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations.

See also [FAQ 45](#) guidance. This FAQ guidance stipulates that a sufficient response includes:

- (Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.
- (Q2, #6) If the application of the NQTL turns on specific decisions in administration of benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s)
- (Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.

This FAQ guidance stipulates what plans and issuers should avoid:

- (Q 3, # 5) Reference to factors and evidentiary standards that were defined or applied in a quantitative manner, without the precise definitions, data, and information necessary to assess their development or application.

Issuer Response:

Design and Application:

The Pharmacy and Therapeutics (P&T) Committee participants include independent, actively practicing physicians and clinical pharmacists from across the U.S. The committee meets six times per year to examine the safety and efficacy of new drugs and biologics as well as clinical updates to

drugs and biologics previously reviewed by the committee. The P&T Committee is designed to ensure an unbiased clinical perspective for the formulary evaluation process from practicing physicians and pharmacists reflecting a variety of practice specialties.

As previously mentioned, the Cigna Healthcare Value Assessment Committee (“HVAC”) is a chartered committee comprised of voting and non-voting representatives across various business units such as clinical, medical, and business leadership that is duly authorized by Cigna Healthcare to make decision regarding coverage treatment of Drug Products based on clinical finding provided by the P&T Committee, including, but not limited to, decisions regarding tier placement and application of utilization management.

In order to determine application of factors the Pharmacy and Therapeutics Committee determines what drugs should be covered based on the approval status of a drug and the clinical information related to efficacy of the drug. The sources for clinical guidelines are clinical findings case studies, peer-reviewed journals, Risk Evaluation and Mitigation Strategy (REMS), primary medical literature; published data from clinical trials; clinical practice guidelines and FDA product information.

Based upon the P&T committee’s decision, in order to determine application of factors, HVAC relies upon multiple sources including but not limited to expert internal and external clinical evidence documentation, information provided from pharmaceutical manufacturers, the FDA, and information gleaned from external clinical bodies and industry groups. The HVAC considers and follows the same processes for both MH/SUD and M/S drugs in its policy and formulary decisions.

Methodology for the Application of Pharmacy Services NQTL

Cigna only applies the Pharmacy Services NQTL to a subset, as not all prescription drugs require utilization management. Utilization management requirements such as prior authorization (including quantity limits), and step therapy apply to certain prescription drugs to ensure the prescribed drugs are medically necessary to treat the enrollee’s condition. Cigna’s prior authorization, step therapy, or quantity limit requirements were developed without regard to whether the prescription drugs are prescribed to treat a M/S condition or a MH/SUD condition.

The Company follows the same processes for M/S and MH/SUD drug to ensure fair and equitable treatment. This is evidenced in the Pharmacy and Therapeutics “P&T” committee policy and Healthcare Value Assessment Committee “HVAC” policy for all drugs when it makes utilization decisions concerning new or existing drugs. The process does not distinguish between drugs used to treat mental health and substance use disorders versus all other drugs.

First, the Pharmacy and Therapeutics Committee is an external committee whose sole purpose is to evaluate drugs that must be included on the Company’s and respective plan’s formularies. The Pharmacy and Therapeutics Committee is made up of independent external healthcare professionals, actively practicing physicians and pharmacists, with particular qualifications in various areas of medicine and healthcare (including multiple medical specialties and pharmacy). The Committee determines what drugs should be covered based on the approval status of a drug and the clinical information related to efficacy of the drug.

Second, the Company maintains a Healthcare Policy & Criteria Committee (“HVAC”), composed of internal company employees primarily made up of medical directors and other healthcare professionals from across the Company and areas of practice. This committee is responsible for taking recommendations and findings from the P&T Committee and translating them into actionable coverage policy and formulary decisions. To make these decisions, the committee relies upon multiple sources including but not limited to expert internal and external clinical evidence documentation, information provided from pharmaceutical manufacturers, the FDA, and information gleaned from external clinical bodies and industry groups. The HVAC considers and follows the same processes for both MH/SUD and M/S drugs in its policy and formulary decisions.

Finally, as a drug enters the marketplace and is approved for human use, the drug will move through the above groups. Determination of whether a drug is covered or not covered is not predicated upon whether the drug is used for mental health vs. another condition. Rather, the drug is reviewed to determine safety and efficacy, does it achieve the desired outcomes, and what is the best manner to achieve access and coverage based on the individual characteristics of the drug.

Pharmacy Experts Qualifications:

The assessment of qualifications of experts and the description of any variance in the use of experts, for both Cigna Coverage Review Department (CCRD) and the National Appeals Organizations (NAO), is defined and justified as forth below.

CCRD and National Appeals Organization are two separate entities, tasked with separate purposes and responsibilities. The clinical expertise on the CCRD is licensed pharmacists and physicians. The pharmacists on the CCRD team are all licensed to practice by a state board of pharmacy and graduates of an accredited school of pharmacy.

As for the National Appeals Organization, under MH/SUD, every behavioral health MD is board certified. All Behavioral Health Psychiatrists are Board Certified. Some hold Board Certification in General Psychiatry, Child/Adolescent Psychiatry, Addiction Psychiatry, and Forensic Psychiatry. Some hold certificates for multiple boards.

Under M/S, current board certification for Cigna Appeal Reviewers are as follows: Allergy and Immunology, Anesthesiology, Cardiovascular Disease, Chiropractic Medicine, Clinical Genetics, Colon and Rectal Surgery, Critical Care Medicine, Dermatology, Emergency Medicine, Endocrinology, Diabetes and Metabolism, Family Medicine, Gastroenterology, General Surgery, Geriatric Medicine, Hospice and Palliative Medicine, Infectious Disease, Internal Medicine, Medical Oncology, Nephrology, Neurological Surgery, Neurology, Neurology, Clinical Neurophysiology, Neurology, Neuromuscular Medicine, Neurology, Sleep Medicine, Obstetrics and Gynecology, Orthopedic Surgery, Osteopathic Manipulative Treatment, Otolaryngology, Neurotology, Pediatric Critical Care Medicine, Pediatrics, Physical Medicine and Rehabilitation, Plastic Surgery, Pulmonary Disease, Rheumatology, Thoracic and Cardiac Surgery.

Relationship Between Factors

Any of the factors outlined in step 2 may be considered in the decision to apply prior authorization,

step therapy, and/or quantity limits. The factor that is given more weight is patient safety.

Step 4: Demonstration of comparability and stringency as written.

See [45 CFR 146.137\(c\)\(4\)](#). The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH or SUD are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. The comparative analysis must include, with respect to the NQTL and the factors used in designing and applying the NQTL:

- (1) Documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH or SUD benefits and medical/surgical benefits in a classification, including, as relevant;
 - (A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the NQTL applies, MH or SUD benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the NQTL would or would not apply; and
 - (B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;
- (2) In each classification in which the NQTL applied to MH or SUD benefits, comparison of how the NQTL, as written, is designed and applied to MH or SUD benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the NQTL or that address the application of the NQTL;
- (3) Documentation demonstrating how the factors are comparably applied, as written, to MH or SUD benefits and medical/surgical benefits in each classification to determine which benefits are subject to the NQTL; and
- (4) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the NQTL, or the application of the NQTL, to MH or SUD benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including
 - (A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;
 - (B) In the design of the factors or evidentiary standards; or
 - (C) In the application or design of the NQTL.

See also [FAQ 45](#) guidance that states that the following is necessary for a sufficient response:

- (Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.
- (Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).
- (Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.

This FAQ guidance stipulates what plans and issuers should avoid::

- (Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.
- (Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.
- (Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.
- (Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Issuer Response:

As Written:

Cigna has assessed its utilization management operational processes applied to MH/SUD or M/S drugs, and confirmed that the operational policies are identical, as-written, and do not distinguish between whether a drug is used to treat an MH/SUD or M/S condition. Moreover, the clinical P&T Committee includes among its membership independently practicing physicians representing a range of clinical specialties, including a psychiatrist that offers MH/SUD expertise when assigning clinical designations to drugs that establish the clinical guidelines and standards that Cigna operates within when considering other factors like financial assessments in placing drugs on a formulary and, if on a formulary, on a particular tier.

Cigna reviewed its utilization management process, i.e., the actual application of prior authorization, step therapy, non-formulary, or quantity limits to MH/SUD drugs, for compliance with the parity NQTL requirement. With respect to parity compliance as-written, Cigna employed the same utilization review criteria and operational policies and procedures for reviewing

utilization management approval requests. Similarly to its process for formulary management, Cigna reviews coverage requests for MH/SUD and M/S drugs subject to a utilization management requirement using a uniform, consolidated process that leverages identical policies and procedures. A team called the Cigna Coverage Review Department (CCRD) reviews initial utilization review requests based on coverage criteria developed by a uniform approval process, and a team called the National Appeals Organization reviews any appeals of denied drug claims, regardless of whether a drug is an MH/SUD or M/S benefit. Both teams employ identical procedures, including turnaround time requirements for standard and expedited requests, the method by which prescribers can submit utilization management approval requests, the issuance of coverage approval or denial determinations to enrollees and prescribers, and quality/oversight protocols.

Cigna reviews non-formulary and step therapy coverage exception requests for any drug, whether an M/S or MH/SUD benefit, which is non-formulary or subject to a step therapy requirement. The coverage exception process ensures that enrollees for which the covered, preferred alternative drugs are clinically inappropriate can obtain coverage for drugs otherwise subject to non-formulary status or a step therapy requirement. If the enrollee's prescriber demonstrates that the non-formulary or, as applicable, drug subject to step therapy is medically necessary, generally by evidencing that the preferred drug(s) are inappropriate or were ineffective for treating the enrollee's condition, then Cigna approves coverage of the requested drug as medically necessary regardless of the drug's status as an MH/SUD or M/S benefit.

The P&T Committee is composed of voting external clinicians across a number of specialties, including a practicing psychiatrist with MH/SUD expertise, clinical pharmacists and medical directors that perform, among other responsibilities, clinical reviews of drugs to determine whether a drug must be covered on the formulary as a clinical matter. In rendering clinical findings on drugs, the P&T Committee assesses the FDA labeling and, as appropriate and available, clinical practice standards/trends and documentation like clinical literature and guidelines.

Degrees	Board Certifications	Professional Title	Practicing Physician	Practicing Pharmacist
M.D., FACC	Internal Medicine, Cardiology	Doctor	X	
M.D.	Dermatology	Doctor	X	
M.D.	Internal Medicine, Endocrine	Doctor	X	
M.D., MPH	Gastroenterology	Doctor	X	
Bpharm, Pharm.D., BCPS	N/A	Doctor		X
M.D., MPH	Internal Medicine, Geriatrics	Doctor	X	
M.D., MPH	Internal Medicine	Doctor	X	
M.D., MPH, FACP	Internal Medicine	Doctor	X	
M.D.	Neurology	Doctor	X	
M.D., FACOG	Obstetrics & Gynecology	Doctor	X	

M.D.	Internal Medicine, Oncology	Doctor	X	
M.D.	Pediatrics	Doctor	X	
Pharm.D., FCCP, BCPS	N/A	Doctor		X
M.D.	Psychiatry	Doctor	X	
M.D., FCCP	Internal Medicine, Critical Care, Pulmonology	Doctor	X	
M.D.	Internal Medicine, Rheumatology	Doctor	X	

The Healthcare Value Assessment Committee is composed of representatives representing several functional areas of the combined company, including, for example, clinicians and representatives from our sales and economics areas, that have experience with formulary management and is responsible for deciding, within the clinical parameters established by the P&T Committee, which drugs will be covered on the formularies offered by Cigna. The Healthcare Value Assessment Committee clinical expertise related to MH/SUD prescription drugs are Clinical Pharmacy Leadership, Licensed Pharmacist and Medical Director, Senior Medical Director, and Licensed Practitioner.

Healthcare Value Assessment Committee Composition	
Credentials	Education
Registered Pharmacist- Ohio & Nevada	Bachelor of Science in Pharmacy, Master of Business Administration
Registered Pharmacist- New Jersey	Pharm. D – Rutgers University – Ernest Mario School of Pharmacy graduate
Board Certified Internal Medicine and Infectious Disease	UCLA (fellowship)
Board Certified in Physical Medicine & Rehabilitation Certified in Pain Medicine by the American Board of Pain Medicine Certified in Obesity Medicine by the American Board of Obesity Medicine	Medical School: Saint Georges University School of Medicine, Grenada West Indies Transitional Internship: Saint Barnabas Medical Center, Livingston, New Jersey Physical Medicine & Rehabilitation Residency: New York-Presbyterian Hospital, New York, New York Pain Management Fellowship: Cedars Sinai – Institute of Spinal Disorders
Certified in Internal Medicine and Hospice and Palliative medicine.	Albert Einstein College of Medicine, graduation 2007 Residency: UCLA Ronald Regan, 2007-2010
Fellow of Society of Actuaries (FSA) Member of American Academy of Actuaries (MAAA) Chartered Enterprise Risk Analyst (CERA)	University of Michigan – Ann Arbor (2010)
Bachelor of Science, Psychology Master of Business Administration	Northwestern University Kellogg School of Management; Northwestern
Registered Pharmacist- Missouri	St Louis College of Pharmacy University of Health Sciences and Pharmacy in St Louis
Registered Pharmacist- New Jersey, Pennsylvania, Massachusetts	Massachusetts College of Pharmacy

Clinical Process for Approving a Requested Drug

To provide safe, effective, and affordable medication options, Cigna Healthcare requires therapeutic criteria (e.g., diagnosis and specialty prescriber) on some MH/SUD and M/S medications. Patients are able to try a more affordable medication that treats a given condition before progressing to a similar acting, but more expensive medication.

The clinical process for analyzing whether the drug was ineffective, preferred drugs are inappropriate or ineffective for treating the enrollee's condition fall within Pharmacy Utilization Management practices and therefore, subject to prior authorization, step therapy, quantity limits, and/or a non-formulary exception is as follows:

Provider(s) submit an authorization request which is then reviewed by the Cigna Clinician assigned to the case. If evidence is provided that the drug was ineffective for the customer, the customer failed treatment with the preferred brand, or the preferred brand was found ineffective in treating the patient, a determination to approve the medication can be made. This is the exact same process for all drugs whether MH/SUD or M/S.

The comparative analysis of evidence required for the demonstration that the drug was ineffective for the customer, preferred drug(s) are inappropriate or were ineffective for treating the enrollee's condition and therefore one of the below non-preferred brand drugs is required is comparable and no less stringent for MH/SUD medications as compared to M/S medications is set forth below:

PA Examples		
MH/SUD ADHD Stimulants	Med/Surg CGRP Inhibitors	Med/Surg Short Acting Opioids
Adderall® (mixed amphetamine salts) Adderall XR® (mixed amphetamine salts) Adhansia XR™ (methylphenidate) Aptensio XR™ (methylphenidate) Azstarys Cotempla XR-ODT Concerta® (methylphenidate) Daytrana® (methylphenidate) Desoxyn Dexedrine® (dextroamphetamine) Dyanavel® XR Evekeo® (amphetamine) Focalin® (dexmethylphenidate) Methylin® (methylphenidate) Adderall/Adderall XR) Ritalin® (methylphenidate)	Aimovig® (erenumab) Ajovy® (fremanezumab-vfrm) Emgality® (galcanezumab-gnlm)	Acetaminophen/codeine Codeine sulfate Hydrocodone/acetaminophen Hydrocodone/ibuprofen Hydromorphone Levorphanol Meperidine Morphine sulfate Nucynta® Opium Tincture Opium/Belladonna alkaloids Oxycodone hydrochloride Oxycodone/acetaminophen Oxymorphone Tramadol

PA Criteria: Diagnosis of ONE of the following: • Attention Deficit/Hyperactivity Disorder (ADD/ADHD) • Narcolepsy • Adjunctive / Augmentation Treatment for Depression and BOTH of the following: ○ Individual is 18 years of age or older ○ Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) • Fatigue associated with Cancer and/or its treatment • Idiopathic Hypersomnolence where confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders Rationale: High potential for off label use and abuse. High potential for off-label use means that a medication is likely to be prescribed by doctors for conditions or purposes that are not explicitly listed on its FDA-approved label, often due to a lack of alternative treatment options, emerging research suggesting potential benefits in other areas, or the need to treat unique patient situations where standard treatments might not be suitable. Non-FDA approved conditions include: Fatigue associated with Multiple Sclerosis (MS), Neuroenhancement, Weight Loss, illicit use	PA Criteria: Migraine Headache Prevention: • Individual is ≥ 18 years of age; AND • Individual has ≥ 4 migraine headache days per month (prior to initiating a migraine-preventative medication) • If a patient is currently taking the brand name drug (Aimovig, Ajovy, Emgality), the patient has had a significant clinical benefit from the medication, as determined by the prescriber. Episodic Cluster Headache Treatment. • Individual is ≥ 18 years of age; AND • Individual has between one headache every other day and eight headaches per day Additionally, Emgality has the following requirements: • Patient has tried at least one standard prophylactic (preventive) pharmacologic therapy for cluster headache; AND Note: Examples of standard prophylactic (preventive) pharmacologic therapies for cluster headache include lithium, verapamil, melatonin, frovatriptan, prednisone, suboccipital steroid injection, topiramate, and valproate. • According to the prescriber, patient has had inadequate efficacy or has experienced adverse event(s) severe enough to warrant discontinuation of the standard prophylactic (preventive) pharmacologic therapy, according to the prescriber; AND • Preferred product criteria is met for the product(s) as listed below: • Episodic Cluster Headache Treatment. Patient meets ONE of the following (1 or 2): 1. Patient has tried and cannot take ONE of the following (a or b): a. sumatriptan injectable P b. zolmitriptan nasal spray [may require prior authorization] Note: A trial of nasal sumatriptan also counts towards this requirement. • Patient has a contraindication to triptans Rationale: High potential for off label use. High potential for off-label use means that a medication is likely to be prescribed by doctors for conditions or purposes that are not explicitly listed on its FDA-approved	PA Criteria: For the management of acute pain (for example, pain lasting less than 90 days) when ONE of the following criteria are met: • For the management of acute dental pain: Attestation that an initial treatment regimen exceeding 3 days is medically necessary (for example, the individual is not a candidate for less than 3 days of therapy) • For the management of acute non-dental pain: Attestation that an initial treatment regimen exceeding 7 days is medically necessary (for example, the individual is not a candidate for less than 7 days of therapy) For the management chronic pain (for example, pain lasting more than 90 days) when ALL of the following criteria are met: • Failure / inadequate response, contraindication per FDA label, intolerance or not a candidate for nonopioid pharmacologic therapies intended to treat pain • Attestation that the history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP) • Attestation that opioids will be prescribed in accordance with current clinical practice guidelines AND that an assessment of risks, harms, and goals consistent with an opioid agreement (or similar agreement) has been undertaken Rationale: High potential for off-label illicit use and abuse.
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	label, often due to a lack of alternative treatment options, emerging research suggesting potential benefits in other areas, or the need to treat unique patient situations where standard treatments might not be suitable. Non-FDA approved conditions include: Acute Treatment of Migraine, Treatment or Prevention of Cluster Headache (Aimovig, Ajovy), Treatment or Prevention of Hemiplegic Migraine	
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MH/SUD Atypical Antipsychotic Agents		M/S Statins	
Step 1 aripiprazole clozapine clozapine ODT olanzapine/olanzapine ODT paliperidone pimozide quetiapine quetiapine ER risperidone risperidone ODT ziprasidone	Step 2 Clozaril® Fanapt® Invega® Orap® Rexulti® Risperdal®/Risperdal M® Saphris® Seroquel® Seroquel XR® Vraylar™	Step 1 atorvastatin ezetimibe-simvastatin fluvastatin/fluvastatin lovastatin pitavastatin pravastatin rosuvastatin calcium simvastatin	Step 2 Altoprev Lescol
Step Criteria: Requires ONE Step 1 agent Rationale: Large number of low cost-generic offerings in the class; sensitive condition where a single step is clinically appropriate instead of multiple steps		Step Criteria: Requires TWO Step 1 agents Rationale: Large number of low cost-generic offerings in the class; condition where multiple generic steps are clinically appropriate	

QL	
MH/SUD ADHD Stimulants	Med/Surg Analgesics/Migraine
ADDERALL XR	CAFERGOT
ADZENYS XR-ODT	CONZIP
APTENSIO XR	DIHYDROERGOTAMINE MESYLATE
AZSTARYS	ELETRIPTAN HBR
CONCERTA	ELYXYB
COTEMPLA XR-ODT	ERGOTAMINE-CAFFEINE
DAYTRANA	ESGIC

DEXEDRINE	FIORICET
DYANAVEL XR	FROVA
FOCALIN XR	FROVATRIPTAN SUCCINATE
JORNAY PM	IMITREX (sumatriptan)
METADATE CD	KETOROLAC TROMETHAMINE
MYDAYIS	MAXALT
QELBREE	MAXALT MLT
QUILLICHEW ER	MIGRANAL
QUILLIVANT XR	NARATRIPTAN HCL
RELEXXII	NURTEC ODT
RITALIN LA	ONZETRA XSAIL
STRATTERA	QDOLO
XELSTRYM	QULIPTA
VYVANSE	RELPAX
	REYVOW
	RIZATRIPTAN
	SEGLENTIS
	SPRIX
	TOSYMRA
	TREXIMET
	TRUDHESA
	UBRELVY
	ULTRAM (tramadol)
	ZAVZPRET
	ZEMBRACE SYMTOUCH
	ZOMIG (zolmitriptan)
	ZOMIG ZMT (zolmitriptan ODT)
Rationale: High potential for off label use and abuse. Non-FDA approved conditions include: Fatigue associated with multiple sclerosis, Neuroenhancement, weight loss, illicit use	Rationale: High potential for off label use. High potential for fraud, waste, and abuse.

Exception Process

An exception is applied on a case-by-case basis. The exception process allows a clinician to deem the request approvable based on the clinical information given and the formulary exception criteria outlined below. A clinician may approve requests for a drug, product, or service if it meets established criteria or, in their clinical judgment, and the drug is being used appropriately. The aforementioned established criteria are provided above, and the established criteria means any criteria documented in any of Cigna's Coverage Policies pertaining to a drug or drug class. The exception criteria are based on FDA indications, FDA labeling and clinical data. This exception process may be applied to any drug, product, service, and is treated the same way whether it be MH/SUD or M/S.

Step 5: Demonstration of comparability and stringency in operation.

See [45 CFR 146.137\(c\)\(5\)](#). The comparative analysis must evaluate whether, in any classification, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH or SUD are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. The comparative analysis must include, with respect to the NQTL and the factors used in designing and applying the NQTL:

- (1) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH or SUD benefits in a classification are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying the NQTL with respect to medical/surgical benefits, including:
 - (A) An explanation of any methodology or underlying data used to demonstrate the application of the NQTL, in operation;
 - (B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the MH or SUD benefits and medical/surgical benefits to which the NQTL is applicable;
 - (C) With respect to an NQTL for which relevant data is temporarily unavailable as described in Section 146.136(c)(4)(iii)(A)(3)(i) a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and
 - (D) With respect to an NQTL for which no data exist that can reasonably assess any relevant impact of the NQTL on relevant outcomes related to access to MH and SUD benefits and medical/surgical benefits as described in Section 146.136(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the BQTL's impact, an explanation of why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the NQTL complies with Section 146.136(c)(4)(iii)(A);
- (2) Identification of the relevant data collected and evaluated, as required under Section 146.136(c)(4)(iii)(A);
- (3) Documentation of the outcomes that resulted from the application of the NQTL to MH or SUD benefits and medical/surgical benefits, including:
 - (A) The evaluation of relevant data as required by Section 146.136(c)(4)(iii)(A)];
 - (B) A reasoned justification and analysis that explains why the plan or issuer

concluded that any differences in the relevant data do or do not suggest the NQTL contributes to material differences in access to MH or SUD benefits as compared to medical/surgical benefits, in accordance with Section 146.136(c)(4)(iii)(B)(2);

- (4) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii), including:
 - (A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to MH or SUD benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the NQTL; and
 - (B) To the extent differences in access to MH or SUD benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate MH and SUD benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply an NQTL, documentation explaining how any such differences are attributable to those standards or measures, as required by Section 146.136(c)(4)(iii)(B)(2)(ii); and
- (5) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to MH or SUD benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under Section 146.136(c)(4)(iii)(B)(1) to address material differences to comply, in operation with Section 146.136(c)(4), including as applicable:
 - (A) A reasoned explanation of any material differences in access to MH or SUD benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and
 - (B) For a plan or issuer designing and applying one or more NQTLs related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network MH and SUD benefits as compared to in-network medical/surgical benefits, including those listed in 146.136(c)(4)(iii)(C).

See also [FAQ 45](#) guidance that states that the following is necessary for a sufficient response:

- (Q2, #5) The analyses, as documented, should explain whether there is any variation

in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.

- (Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).
- (Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.

This FAQ guidance stipulates what plans and issuers should avoid:

- (Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.
- (Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.
- (Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.
- (Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Issuer Response:

In Operation:

On an annual basis, Cigna reviews applicable operational data with Subject Matter Experts to assess ongoing relevance and makes updates as necessary.

In terms of in-operation parity compliance, Cigna confirmed that all drugs, whether MH/SUD or M/S drugs, that the P&T Committee designates must be covered are, in fact, covered on the formulary, and all drugs' coverage conform to other P&T Committee clinical parameters dictating the circumstances under which a drug can be preferred over another drug through tier placement or subject to step therapy requirements mandating use of one drug over another for coverage purposes. Moreover, for its IFP formularies Cigna's coverage of MH/SUD and M/S drugs all conform to the aforementioned standards established for Tier 1, Tier 2, Tier 3, and, as applicable for policyholders that elect to offer a specialty drug tier, Tier 4 placement status.

Cigna has also assessed as follows across the VA IFP formularies. First, the percentage of MH/SUD drug NDCs are covered on v. off-formulary as compared to M/S drug National Drug Codes (NDCs) under such formularies is higher (14.59% of MH/SUD and 19.47% of M/S drug NDCs each are covered off-formulary). Second, a lower, percentage of MH/SUD drug NDCs are covered on the higher cost, non-preferred brand tier (Tier 4 for 4 Tier or Tier 5 for 5 Tier) of the VA IFP formulary.

M/S vs MH/SUD Drugs -PA QL ST Narrative

As shown in the data tables below the percentage of MH/SUD on the formulary that are generic is higher across all formularies as compared to M/S drugs. MH/SUD generic drugs on the formulary are a higher percentage than M/S because again M/S has more specialty drugs and brand name products. However, MH/SUD drug products have been in the market for decades and have generics available, partly due to drug patents and when generics can be made per patent law. As compared to M/S drugs are still branded and hold patents. When comparing the new drug market for M/S drugs versus MH/SUD drugs most new drugs are for M/S, not MH/SUD, for example, new oncology drugs; therefore, that is one reason why there are more generics for MH/SUD.

VA IFP 4 Tier Formulary	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	6,011		30,401	
Total Non-Specialty Drugs	5,988	99.62%	26,396	86.83%
On Formulary	5,134	85.41%	24,482	80.53%
Non-Formulary	877	14.59%	5,919	19.47%
Tier 1 Drugs	4,405	73.28%	18,797	61.83%
Tier 2 Drugs	353	5.87%	2,086	6.86%
Tier 3 Drugs	1,248	20.76%	7,567	24.89%
Tier 4 Drugs	5	0.08%	1,951	6.42%
Drugs requiring Prior Auth	218	3.63%	2,871	9.44%
Drugs requiring Step Therapy	26	0.43%	35	0.12%
Drugs requiring Quantity Limits	2,677	44.54%	6,077	19.99%

VA IFP 5 Tier Formulary	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	6,011		30,401	
Total Non-Specialty Drugs	5,988	99.62%	26,396	86.83%
On Formulary	5,134	85.41%	24,482	80.53%
Non-Formulary	877	14.59%	5,919	19.47%

Tier 1 Drugs	821	13.66%	4,441	14.61%
Tier 2 Drugs	3,584	59.62%	14,356	47.22%
Tier 3 Drugs	353	5.87%	2,086	6.86%
Tier 4 Drugs	1,248	20.76%	7,567	24.89%
Tier 5 Drugs	5	0.08%	1,951	6.42%
Drugs requiring Prior Auth	218	3.63%	2871	9.44%
Drugs requiring Step Therapy	26	0.43%	35	0.11%
Drugs requiring Quantity Limits	2,677	44.54%	6,077	19.98%

Prior Authorizations:

On the Virginia IFP Formulary, a lower percentage of MH/SUD drugs require prior authorization as compared to M/S.

Step Therapy:

Both M/S and MH/SUD require step therapy for <1% of the non-specialty drugs on the Virginia IFP formulary.

Quantity Limits:

When comparing quantity limits for MH/SUD drugs vs. M/S drugs, Cigna Healthcare places a quantity limit (QL) on a higher percentage of MH/SUD drugs. This difference in percentages between MH/SUD and M/S in this category can be explained by the fact that a higher relative proportion of MH/SUD drugs as compared to M/S drugs present safety concerns, including and especially being recognized as controlled substances under federal law.

Excluded Medications:

On the Virginia IFP Formulary, MH/SUD has a lower percentage of non-formulary drugs as compared to M/S. As seen by this data, Cigna Healthcare is less restrictive with specialty MH/SUD drugs than with specialty M/S medications.

In terms of branded MH/SUD drugs that have been excluded from the formulary, there are no true excluded drugs for MH/SUD that have been excluded from the formulary. There are no drugs that are considered a true exclusion, drugs not covered still have a path to access. Even if a drug is DRT, non-formulary drugs, there is a path for medical necessity via providers. A true exclude is for example over the counter drugs and compound drugs, which are not commercially available and have to be compounded by a pharmacy.

All percentages on the MHP Pharmacy Report Summary are calculated by dividing the numerator (total drugs in that subset e.g., PA for M/S) by the total drugs within M/S or MH/SUD. For example,

to calculate Tier 1 on formulary for MH/SUD, use the Virginia IFP MH SUD 01012025 By Formulary, sort column “P” for “1” which is Tier 1 and filter column “Q” for exclusions (“N”) this will provide the total on formulary for Virginia IFP. That process is used to obtain a total on MH/SUD on formulary drugs (numerator) and then divide by the total of all drugs including exclude within MH/SUD (denominator).

Virginia IFP Formulary Design

Column P = Tier Type (Virginia 4Tier/5Tier) filter to determine results by tier	Column Q = Virginia Formulary Status column is used to determine on vs non-formulary	Column S = Utilization Management column is used to determine what type of UM is applied. Ex: To determine PA check all boxes in the filter that have PA
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Cigna is providing the Virginia and IFP book of business pharmacy utilization management results below. The source of the data is the Cigna C360 UM Management system.

2025 Virginia IFP RX UM Book of Business data:

Pharmacy/Prescription Drugs	MH/SUD	MH/SUD Approval and Denial Rate	M/S	M/S Approval and Denial Rate
Total Number of Pharmacy Authorization Requests Received	408		6468	
Total Number of Pharmacy Authorization Requests Denied	115	28.19%	1791	27.69%
Total Number of Pharmacy Authorization Requests Approved	293	71.81%	4677	72.31%
Total Number of Pharmacy PA requests Received	25		2223	
Total Number of Pharmacy PA requests Denied	7	28.00%	547	24.61%
Total Number of Pharmacy PA Approved	18	72.00%	1676	75.39%
Total Number of Step-Therapy or Fail-First Requests Received	72		101	
Total Number of Step-Therapy or Fail-First Requests Denied	6	8.33%	19	18.81%
Total Number of Step-Therapy or Fail-First Requests Approved	66	91.67%	82	81.19%
Total Number of QL Requests Received	51		486	
Total Number of QL requests Denied	10	19.61%	137	28.19%
Total Number of QL requests Approved	41	80.39%	349	71.81%
Total Number of DRT/NonFormulary Requests Received	260		3658	
Total Number of DRT/NonFormulary Requests Denied	92	35.38%	1088	29.74%
Total Number of DRT/NonFormulary Requests Approved	168	64.62%	2570	70.26%

Total Number of On Formulary Requests Received	148		2810	
Total Number of On Formulary Requests Denied	23	15.54%	703	25.02%
Total Number of On Formulary Requests Approved	125	84.46%	2107	74.98%

The VA IFP data for 2025 shows comparable approval and denial rates across all M/S and MH/SUD authorization requests (72.31% approval and 71.81% approval respectively). MH/SUD had a slightly higher prior authorization denial rate than M/S; however, the MH/SUD request volume was substantially lower (25 requests compared with 2,223 M/S requests). Accordingly, the MH/SUD denial rate is more sensitive to individual case outcomes and should be interpreted in the context of the limited volume

2025 Cigna IFP RX UM Book of Business data:

Pharmacy/Prescription Drugs	MH/SUD	MH/SUD Approval and Denial Rate	M/S	M/S Approval and Denial Rate
Total Number of Pharmacy Authorization Requests Received	5,300		78,100	
Total Number of Pharmacy Authorization Requests Denied	1,576	29.74%	22,679	29.04%
Total Number of Pharmacy Authorization Requests Approved	3,724	70.26%	55,421	70.96%
Total Number of Pharmacy PA requests Received	423		27,870	
Total Number of Pharmacy PA requests Denied	236	55.79%	7,178	25.76%
Total Number of Pharmacy PA Approved	187	44.21%	20,692	74.24%
Total Number of Step-Therapy or Fail-First Requests Received	1,183		2,418	
Total Number of Step-Therapy or Fail-First Requests Denied	195	16.48%	297	12.28%
Total Number of Step-Therapy or Fail-First Requests Approved	988	83.52%	2,121	87.72%
Total Number of QL Requests Received	631		5,716	
Total Number of QL requests Denied	115	18.23%	1,650	28.87%
Total Number of QL requests Approved	516	81.77%	4,066	71.13%
Total Number of DRT/NonFormulary Requests Received	3,063		42,096	
Total Number of DRT/NonFormulary Requests Denied	1,030	33.63%	13,554	32.20%
Total Number of DRT/NonFormulary Requests Approved	2,033	66.37%	28,542	67.80%
Total Number of On Formulary Requests Received	2,237		36,004	
Total Number of On Formulary Requests Denied	546	24.41%	9,125	25.34%

Total Number of On Formulary Requests Approved	1,691	75.59%	26,879	74.66%
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On formulary includes Prior Authorization, Step Therapy and Quantity Limits.

Approval means coverage for the drug and denial means that the request for utilization management review and ultimate approval of drug was not approved.

In reviewing the 2025 Cigna IFP book of business data, MH/SUD had a comparable overall denial percentage when compared to M/S (29.74% and 29.04% respectively). MH/SUD does have a higher denial percentage for prior authorization requests and a slightly higher denial percentage for step therapy requests.

The higher initial MH/SUD denial percentage is explained by the clinical and safety characteristics of the underlying drug categories and the documentation needed to confirm coverage criteria, not by a more stringent application of prior authorization or step therapy to MH/SUD drugs. The same factors, evidentiary standards, review processes, and exception pathways apply to MH/SUD and M/S drugs. In addition, because the reported denial data reflects initial determinations, it does not necessarily represent final coverage outcomes after additional clinical documentation, reconsideration, or appeal.

Step 6: Findings and conclusions.

See [45 CFR 146.137\(c\)\(6\)](#). The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to MH or SUD benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

- (1) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of Section 146.136(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;
- (2) A reasoned and detailed discussion of the findings and conclusions described in (1) above;
- (3) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions in (1) above not otherwise discussed in the comparative analysis;
- (4) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and
- (5) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's

qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the NQTL applicable to both MH or SUD benefits and medical/surgical benefits.

See also the [FAQ 45](#) guidance, which states that a sufficient response should include:

- (Q 2, # 8) A reasoned discussion of the plan's or issuer's findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, factors, and sources identified above within each affected classification, and their relative stringency, both as applied and as written. This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA.

This FAQ guidance stipulates what plans and issuers should avoid:

- (Q 3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.

Issuer Conclusions and Findings:

The measures that Cigna employs to ensure the comparability design and application of the utilization management NQTLs to MH/SUD and M/S prescription drug benefits are to ensure that the written policies governing whether, and, if so, how, utilization management NQTLs are applied to MH/SUD or M/S drugs are uniform (i.e., turnaround times, qualifications of reviewers), to ensure that the in-writing process and standards relied on are comparable irrespective of the underlying use of the drug. Moreover, Cigna assesses outcomes data, including denial rates and incidence rates for the application of utilization management NQTLs (i.e., the proportion of MH/SUD and M/S drugs that are subject to utilization management), to ensure that there are no significant discrepancies in the outcomes of the NQTLs' application across MH/SUD and M/S benefits that warrant further scrutiny.

Cigna has not delegated the administration of a benefit subject to the applicable NQTL to another entity.

The application of uniform written factors and evidentiary standards for deciding whether to apply a utilization management NQTL to MH/SUD or M/S benefits, and the use of a uniform process for deciding whether, and how, to apply utilization management NQTLs to drug benefits that includes comparable expertise in MH/SUD treatment (e.g., a psychiatrist among the P&T Committee voting membership), as well as the comparable denial rates in utilization management outcomes and, generally, incidence of utilization management for MH/SUD and M/S drugs, supports a finding of compliance with the NQTL requirement. And to the extent a discrepancy in outcomes, including the higher incidence in the application of step therapy requirements and quantity limits, a form of prior authorization, to MH/SUD drugs, was identified it is explicable based on the higher proportional presence of the requisite factors relied on to

trigger application of step therapy or quantity limits to MH/SUD drugs. More specifically, while the incidence of step therapy requirements was comparable, i.e., there was not a significant disparity in the incidence of application of step therapy applied to MH/SUD drugs as-compared to M/S drugs, there was nonetheless a higher incidence of step therapy applied to MH/SUD drugs because the factors used to apply step therapy to drugs were present for a higher incidence of MH/SUD drugs.

Further, under Cigna's drug utilization management programs a comparable, and, in this case, lower proportion of MH/SUD drugs are subject to prior authorization (excluding quantity limits) as compared to M/S drugs. A notably higher proportion of MH/SUD drugs are subject to quantity limits, a form of prior authorization, as compared to M/S drugs under the utilization management program, but this discrepancy is the justifiable outcome of the application of the same factors and evidentiary standards described earlier in this analysis. For instance, a higher relative proportion of MH/SUD drugs as compared to M/S drugs present safety concerns, including and especially being recognized as controlled substances under federal law. It is also notable from a stringency perspective that a quantity limit, as distinguished from a prior authorization, is a less stringent form of prior authorization because it only functions to require authorization if the prescription exceeds a specified dosage/amount of the drug. If a drug is merely subject to a quantity limit, only the appropriateness of the dosage/amount is reviewed for Medical Necessity, and not, for example, the appropriateness of use for the condition in question. When assessed exclusive of quantity limits, the less stringent form of prior authorization, a higher proportion of M/S drugs are subject to prior authorization as compared to MH/SUD drugs.

This version of the analysis was drafted and performed in 2026 based upon Cigna's and Virginia 2025 IFP book-of-business data, by members of the legal, compliance, and various business teams, including the following individuals:

Mental Health Parity Legal Team including:

Managing Counsel;

Counsel;

Associate Senior Counsel; and

Legal Compliance Senior Advisor

Mental Health Parity Compliance team including:

Legal Compliance Senior Manager;

Legal Compliance Senior Advisor

Pharmacy subject matter experts including:

Operations Senior Manager;

Clinical Pharmacist;

Legal Compliance Senior Advisor