

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 M.C. Dean, Inc. 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 M.C. Dean, Inc. plan certificate and states as follows:

M.C. Dean, Inc. Plan Language
Limitations For most Prescription Drug Products you and your Dependent pay only the cost sharing detailed in The Schedule of Prescription Drug Benefits. However, in the event you or your Dependent insist on a more expensive Brand Drug where a Therapeutic Equivalent Generic Drug is available, you will be financially responsible for an Ancillary Charge, in addition to any required Brand Drug Copayment and/or Coinsurance. In this case, the Ancillary Charge will not apply to your Deductible, if any, or Out-of-Pocket Maximum. However, in the event your Physician determines that the Generic Drug is not an acceptable alternative for you (and indicates Dispensed as Written on the Prescription Order or Refill), you will only be responsible for payment of the appropriate Brand Drug Coinsurance and/or Copayment after satisfying your Deductible, if any. Your plan includes a Brand Drug for Generic Drug dispensing program. This program allows certain Brand Drugs to be dispensed in place of the Therapeutic Equivalent Generic Drug at the time your Prescription Order or Refill is processed by a participating Pharmacy. Brand Drug for Generic Drug substitution will occur only for certain Brand Drugs included in the program. When this substitution program is applied, the participating Pharmacy will dispense the Brand Drug to you in place of the available Generic Drug. You will be responsible for payment of

only a Generic Drug Copayment and/or Coinsurance, after satisfying your Deductible, if any.¹

Prior Authorization Requirements

Coverage for certain Prescription Drug Products prescribed to you requires your Physician to obtain prior authorization from Cigna or its Review Organization. The reason for obtaining prior authorization from Cigna is to determine whether the Prescription Drug Product is Medically Necessary in accordance with Cigna's coverage criteria. Coverage criteria for a Prescription Drug Product may vary based on the clinical use for which the Prescription Order or Refill is submitted, and may change periodically based on changes in, without limitation, clinical guidelines or practice standards, or market factors.

If Cigna or its Review Organization reviews the documentation provided and determines that the Prescription Drug Product is not Medically Necessary or otherwise excluded, your plan will not cover the Prescription Drug Product. Cigna, or its Review Organization, will not review claims for excluded Prescription Drug Products or other services to determine if they are Medically Necessary, unless required by law.

When Prescription Drug Products that require prior authorization are dispensed at a Pharmacy, you or your prescribing Physician are responsible for obtaining prior authorization from Cigna. If you do not obtain prior authorization from us before the Prescription Drug Product is dispensed by the Pharmacy, you can ask us to consider reimbursement after you pay for and receive the Prescription Drug Product. You will need to pay for the Prescription Drug Product at the Pharmacy prior to submitting a reimbursement request.

When you submit a claim on this basis, you will need to submit a paper claim using the form that appears on the website shown on your ID card.

If a prior authorization request is approved, your Physician will receive confirmation. The authorization will be processed in the claim system to allow you to have coverage for the Prescription Drug Product. The length of the authorization may depend on the diagnosis and the Prescription Drug Product. The authorization will at all times be subject to the plan's terms of coverage for the Prescription Drug Product, which may change from time to time. When your Physician advises you that coverage for the Prescription Drug Product has been approved, you can contact a Pharmacy to fill the covered Prescription Order or Refill.

If the prior authorization request is denied, your Physician and you will be notified that coverage for the Prescription Drug Product is not authorized. If you disagree with a coverage decision, you may appeal that decision in accordance with the provisions of the plan by submitting a written request stating why the Prescription Drug Product should be covered.

Step Therapy

Certain Prescription Drug Products are subject to step therapy requirements. This means that in order to receive benefits for such Prescription Drug Products you are required to try a different Prescription Drug Product(s) first unless you satisfy the plan's exception criteria. You may identify whether a particular Prescription Drug Product is subject to step therapy requirements at the website shown on your ID card or by calling member services at the telephone number on your ID card.

If your treating health care provider submits a request for a step therapy exception determination, the request must state the circumstance that qualifies for a step therapy exception.

We will respond to the exception request with our decision within three (3) business days of receipt of the exception request.

In cases where emergency circumstances exist, we will respond with our decision within 24 hours of receipt of an exception request.

If we grant an exception request, we will authorize coverage for the Prescription Drug Product.

You may request an appeal of any step therapy exception denial by following the appeals process.

Contraceptive Drugs

FDA-approved, self-administered hormonal contraceptives will be covered for up to a 12-month supply.

Supply Limits

Benefits for Prescription Drug Products are subject to the supply limits that are stated in The Schedule. For a single Prescription Order or Refill, you may receive a Prescription Drug Product up to the stated supply limit. Some products are subject to additional supply limits, quantity limits or dosage limits based on coverage criteria that have been approved based on consideration of the P&T Committee's clinical findings. Coverage criteria are

subject to periodic review and modification. The limit may restrict the amount dispensed per Prescription Order or Refill and/or the amount dispensed per month's supply, or may require that a minimum amount be dispensed. You may determine whether a Prescription Drug Product has been assigned a dispensing supply limit or similar limit or requirement at the website shown on your ID card or by calling member services at the telephone number on your ID card.

Medication Synchronization

Prescription Drug Products that are dispensed by a Network Pharmacy for a partial supply will be covered if the prescribing provider or the pharmacist determines the Prescription Order or Refill to be in the best interest of you or your Dependent, and you or your Dependent requests or agrees to a partial supply for the purpose of synchronizing medications. Early refills of Prescription Drug Products will be covered for the purposes of synchronizing medications.

Specialty Prescription Drug Products

Benefits are provided for Specialty Prescription Drug Products. If you require Specialty Prescription Drug Products, you may be directed to a Designated Pharmacy with whom Cigna has an arrangement to provide those Specialty Prescription Drug Products.

Designated Pharmacies

If you require certain Prescription Drug Products, including, but not limited to, Specialty Prescription Drug Products, we may direct you to a Designated Pharmacy with whom we have an arrangement to provide those Prescription Drug Products. If you are directed to a Designated Pharmacy and you choose not to obtain your Prescription Drug Product from a Designated Pharmacy, you may receive reduced or no coverage for the Prescription Drug Product. Refer to The Schedule for further information.

Newly FDA Approved Prescription Drug Products

During the time Cigna reviews newly FDA-approved Prescription Drug Products for appropriate placement on its formulary, your physician may request a non-formulary coverage exception by submitting a prior authorization for the drug product under formulary review. Cigna or its Review Organization will review the individual request, along with all necessary information submitted, to determine coverage based on Medical Necessity. If authorized, the newly approved Prescription Drug Product will be covered at the applicable coverage tier as set forth in The Schedule. In placing newly FDA-approved Prescription Drugs Products on its formulary, Cigna considers clinical recommendations from its independent panel of practicing physicians and pharmacists that make up its P&T Committee in addition to pharmacoeconomic data. Consideration for formulary placement typically occurs within 180 days of a drug being marketed.²

Exclusions

Coverage exclusions listed under the "Exclusions, Expenses Not Covered and General Limitations" section also apply to benefits for Prescription Drug Products. In addition, the exclusions listed below apply to benefits for Prescription Drug Products. When an exclusion or limitation applies to only certain Prescription Drug Products, you can access the internet through the website shown on your ID card or call member services at the telephone number on your ID card for information on which Prescription Drug Products are excluded.

- coverage for Prescription Drug Products for the amount dispensed (days' supply) which exceeds the applicable supply limit, or is less than any applicable supply minimum set forth in The Schedule, or which exceeds quantity limit(s) or dosage limit(s) set by the P&T Committee.
- more than one Prescription Order or Refill for a given prescription supply period for the same Prescription Drug Product prescribed by one or more Physicians and dispensed by one or more Pharmacies.
- Prescription Drug Products dispensed outside the jurisdiction of the United States, except as required for emergency or Urgent Care treatment.
- Prescription Drug Products which are prescribed, dispensed or intended to be taken by or administered to you while you are a patient in a licensed Hospital, Skilled Nursing Facility, rest home, rehabilitation facility, or similar institution which operates on its premises or allows to be operated on its premises a facility for dispensing pharmaceutical products.
- Prescription Drug Products furnished by the local, state or federal government (except for a Network

Pharmacy owned or operated by a local, state or federal government).

- any product dispensed for the purpose of appetite suppression (anorectics) or weight loss.
- prescription and non-prescription supplies other than supplies covered as Prescription Drug Products.
- vitamins, except prenatal vitamins that require a Prescription Order or Refill, unless coverage for such product(s) is required by federal or state law.
- medications used for cosmetic purposes, including, without limitation, medications used to reduce wrinkles, medications used to promote hair growth and fade cream products.
- Prescription Drug Products as a replacement for a previously dispensed Prescription Drug Product that was lost, stolen, broken or destroyed.
- Prescription Drug Products used for the treatment of infertility.
- Medical Pharmaceuticals covered solely under the plan's medical benefits.
- any ingredient(s) in a compounded Prescription Drug Product that has not been approved by the U.S. Food and Drug Administration (FDA).
- medications available over-the-counter that do not require a Prescription Order or Refill by federal or state law before being dispensed, unless state or federal law requires coverage of such medications or the over-the-counter medication has been designated as eligible for coverage as if it were a Prescription Drug Product.
- certain Prescription Drug Products that are a Therapeutic Equivalent or Therapeutic Alternative to an over-the-counter drug(s), or are available in over-the-counter form. Such coverage determinations may be made periodically, and benefits for a Prescription Drug Product that was previously excluded under this provision may be reinstated at any time.
- any product for which the primary use is a source of nutrition, nutritional supplements, or dietary management of disease, even when used for the treatment of Sickness or Injury, unless coverage for such product(s) is required by federal or state law.
- medications used for travel prophylaxis, immunization agents, virus detection testing, virus antibody testing, biological products for allergy immunization, biological sera, blood, blood plasma and other blood products or fractions unless specifically identified on the Prescription Drug List.
- certain Prescription Drug Products that are a Therapeutic Equivalent or Therapeutic Alternative to another covered Prescription Drug Product(s). Such coverage determinations may be made periodically, and benefits for a Prescription Drug Product that was previously excluded under this provision may be reinstated at any time.
- medications that are experimental, investigational or unproven as described under the "General Exclusion and Limitations" section of your plan's certificate.

Reimbursement/Filing a Claim

Retail Pharmacy

When you or your Dependents purchase your Prescription Drug Products through a Network Pharmacy, you pay any applicable Copayment, Coinsurance, or Deductible shown in The Schedule at the time of purchase. You do not need to file a claim form for a Prescription Drug Product obtained at a Network Pharmacy unless you pay the full cost of a Prescription Drug Product at a Network Pharmacy and later seek reimbursement for the Prescription Drug Product under the plan. For example, if you must pay the full cost of a Prescription Drug Product to the retail Network Pharmacy because you did not have your ID card, then you must submit a claim to Cigna for any reimbursement or benefit you believe is due to you under this plan. If, under this example, your payment to the retail Network Pharmacy for the covered Prescription Drug Product exceeds any applicable copay, then you will be reimbursed the difference, if any, between the applicable copay and the Prescription Drug Charge for the Prescription Drug Product.

If you obtain a covered Prescription Drug Product dispensed by a non-Network Pharmacy, then you must pay the non-Network Pharmacy for the Prescription Drug Product and then submit a claim to Cigna for any reimbursement or benefit you believe is due to you under this plan. You can obtain a claim form through the website shown on your ID card or by calling member services at the telephone number on your ID card.³

Claim Determination Procedures under ERISA

The following complies with federal law. Provisions of applicable laws of your state may supersede.

Procedures Regarding Medical Necessity Determinations

In general, health services and benefits must be Medically Necessary to be covered under the plan. The procedures for determining Medical Necessity vary, according to the type of service or benefit requested, and the type of health plan.

Medical Necessity determinations are made on a preservice, concurrent, or postservice basis, as described below:

Certain services require prior authorization in order to be covered. The Certificate describes who is responsible for obtaining this review. You or your authorized representative (typically, your health care professional) must request prior authorization according to the procedures described below, in the Certificate, and in your provider's network participation documents as applicable.

When services or benefits are determined to be not covered, you or your representative will receive a written description of the adverse determination, and may appeal the determination. Appeal procedures are described in the Certificate, in your provider's network participation documents as applicable, and in the determination notices.

Note: An oral statement made to you by a representative of Cigna or its designee that indicates, for example, a particular service is a Covered Expense, is authorized for coverage by the plan, or that you are eligible for coverage is not a guarantee that you will receive benefits for services under this plan. Cigna will make a benefit determination after a claim is received from you or your authorized representative, and the benefit determination will be based on, your eligibility as of the date services were rendered to you and the terms and conditions of the plan in effect as of the date services were rendered to you.

Preservice Determinations

When you or your representative requests a required prior authorization, Cigna will notify you or your representative of the determination within 15 days after receiving the request. However, if more time is needed due to matters beyond Cigna's control, Cigna will notify you or your representative within 15 days after receiving your request. This notice will include the date a determination can be expected, which will be no more than 30 days after receipt of the request. If more time is needed because necessary information is missing from the request, the notice will also specify what information is needed, and you or your representative must provide the specified information to Cigna within 45 days after receiving the notice. The determination period will be suspended on the date Cigna sends such a notice of missing information, and the determination period will resume on the date you or your representative responds to the notice.

If the determination periods above would seriously jeopardize your life or health, your ability to regain maximum function, or in the opinion of a health care professional with knowledge of your health condition, cause you severe pain which cannot be managed without the requested services, Cigna will make the preservice determination on an expedited basis. Cigna will defer to the determination of the treating health care professional regarding whether an expedited determination is necessary. Cigna will notify you or your representative of an expedited determination within 72 hours after receiving the request.

However, if necessary information is missing from the request, Cigna will notify you or your representative within 24 hours after receiving the request to specify what information is needed. You or your representative must provide the specified information to Cigna within 48 hours after receiving the notice. Cigna will notify you or your representative of the expedited benefit determination within 48 hours after you or your representative responds to the notice. Expedited determinations may be provided orally, followed within 3 days by written or electronic notification.

If you or your representative attempts to request a preservice determination, but fails to follow Cigna's procedures for requesting a required preservice determination, Cigna will notify you or your representative of the failure and describe the proper procedures for filing within 5 days (or 24 hours, if an expedited determination is required, as described above) after receiving the request. This notice may be provided orally, unless you or your representative requests written notification.

Notice of Adverse Determination

Every notice of an adverse benefit determination will be provided in writing or electronically, and will include all of the following that pertain to the determination: information sufficient to identify the claim including, if applicable, the date of service, provider and claim amount; diagnosis and treatment codes, and their meanings;

the specific reason or reasons for the adverse determination including, if applicable, the denial code and its meaning and a description of any standard that was used in the denial; reference to the specific plan provisions on which the determination is based; a description of any additional material or information necessary to perfect the claim and an explanation of why such material or information is necessary; a description of the plan's review procedures and the time limits applicable, including a statement of a claimant's rights to bring a civil action under section 502(a) of ERISA following an adverse benefit determination on appeal, (if applicable); upon request and free of charge, a copy of any internal rule, guideline, protocol or other similar criterion that was relied upon in making the adverse determination regarding your claim; and an explanation of the scientific or clinical judgment for a determination that is based on a Medical Necessity, experimental treatment or other similar exclusion or limit; a description of any available internal appeal and/or external review process(es); information about any office of health insurance consumer assistance or ombudsman available to assist you with the appeal process; and in the case of a claim involving urgent care, a description of the expedited review process applicable to such claim.⁴

When You Have A Complaint Or An Appeal

For the purposes of this section, any reference to "you," "your" or "Member" also refers to a representative or provider designated by you to act on your behalf, unless otherwise noted.

We want you to be completely satisfied with the care you receive. That is why we have established a process for addressing your concerns and solving your problems.

Start With Member Services

We are here to listen and help. If you have a concern regarding a person, a service, the quality of care, or contractual benefits, you may call our toll-free number found on your Benefit Identification card and explain your concern to one of our Customer Service representatives. You may also express that concern in writing. Please write to us at the following address:

Cigna
National Appeals Organization (NAO)
P.O. Box 188011
Chattanooga, TN 37422

We will do our best to resolve the matter on your initial contact. If we need more time to review or investigate your concern, we will get back to you as soon as possible, but in any case within 30 days.

If you are not satisfied with the results of a coverage decision, you can start the appeals procedure.

Internal Appeals Procedure

Cigna has a two-step appeals procedure for coverage decisions. To initiate an appeal, you must submit a request for an appeal within 180 days of receipt of a denial notice.

If you appeal a reduction or termination in coverage for an ongoing course of treatment that Cigna previously approved, you will receive, as required by applicable law, continued coverage pending the outcome of an appeal. You should state the reason why you feel your appeal should be approved and include any information supporting your appeal. If you are unable or choose not to write, you may ask to register your appeal by telephone. Call us at the toll-free number or address on your Benefit Identification card, explanation of benefits or claim form.

Level One Appeal

Your appeal will be reviewed and the decision made by someone not involved in the initial decision. Appeals involving Medical Necessity or clinical appropriateness will be considered by a Physician or Dentist reviewer. For all level one appeals we will make a determination within 15 calendar days after we receive an appeal for a pre-service claim, and no later than 30 calendar days for post-service claims. You will be notified of Cigna's decision the earlier of: five business days from the decision; or within 15 calendar days from the receipt of the appeal for pre-service claims, and no later than 30 calendar days from the receipt of the appeal for post-service claims.

Expedited Level One Appeal

You may request that the appeal process be expedited if the time frames under this process would seriously jeopardize your life, health or ability to regain maximum function or, in the opinion of your Physician would

cause you severe pain which cannot be managed without the requested services.

If you request an expedited internal appeal of an adverse determination with Cigna, you are deemed to have exhausted the internal appeal process and may file a request for an expedited external review of the adverse determination at the same time, if otherwise eligible.

Cigna's Physician reviewer or your treating Physician, will decide if an expedited appeal is necessary. When an appeal is expedited, Cigna will respond orally with a decision as soon as possible, not to exceed 72 hours, taking into account medical exigencies. Cigna will respond orally to expedited appeals related to prescriptions for the alleviation of cancer pain within 24 hours of the receipt of all necessary information. We will follow up in writing within 24 hours of the oral response to an expedited appeal.

Level Two Appeal

If you are dissatisfied with our level one appeal decision, you may request a second review. To start a level two appeal, follow the same process required for a level one appeal.

If the appeal involves a coverage decision based on issues of Medical Necessity, clinical appropriateness or experimental treatment, a medical review will be conducted by a Physician reviewer in the same or similar specialty as the care under consideration, as determined by Cigna's Physician reviewer. For all other coverage plan-related appeals, a second-level review will be conducted by someone who was: not involved in any previous decision related to your appeal; and not a subordinate of previous decision makers. Provide all relevant documentation with your second-level appeal request.

For required pre-service and concurrent care coverage determinations, Cigna's review will be completed within 15 calendar days. For post-service claims, Cigna's review will be completed within 30 calendar days. In the event any new or additional information (evidence) is considered, relied upon or generated by Cigna in connection with the level two appeal, Cigna will provide this information to you as soon as possible and sufficiently in advance of the decision, so that you will have an opportunity to respond. Also, if any new or additional rationale is considered by Cigna, Cigna will provide the rationale to you as soon as possible and sufficiently in advance of the decision so that you will have an opportunity to respond.

You will be notified of Cigna's decision (either an approval or denial) of a pre-service claim the earlier of: five business days from the decision; or within 15 calendar days from the receipt of the appeal. For a post-service claim, you will be notified of Cigna's decision the earlier of five business days from the decision; or within 30 days from the receipt of the appeal.

Expedited Level Two Appeal

You may request that the appeal process be expedited if, the time frames under this process would seriously jeopardize your life, health or ability to regain maximum function or in the opinion of your Physician would cause you severe pain which cannot be managed without the requested services; or your appeal involves nonauthorization of an admission, or availability of care, or continuing inpatient Hospital stay, or health care service for which you received emergency services.

If you request an expedited internal appeal of an adverse determination with Cigna, you are deemed to have exhausted the internal appeal process and may file a request for an expedited external review of the adverse determination at the same time, if otherwise eligible.

Cigna's Physician reviewer or your treating Physician will decide if an expedited appeal is necessary. When an appeal is expedited, we will respond orally with a decision as soon as possible, not to exceed 72 hours, taking into account medical exigencies. We will respond orally to expedited appeals related to prescriptions for the alleviation of cancer pain within 24 hours of the receipt of all necessary information. We will follow up in writing within 24 hours of the oral response to an expedited appeal.

Notice of Benefit Determination on Appeal

Every notice of a determination on appeal will be provided in writing or electronically and, if an adverse determination, will include:

- information sufficient to identify the claim;
- the specific reason or reasons for the adverse determination;
- reference to the specific plan provisions on which the determination is based;
- a statement that the claimant is entitled to receive, upon request and free of charge, reasonable access to and copies of all documents, records, and other Relevant Information as defined;
- a statement describing any voluntary appeal procedures offered by the plan and the claimant's right to bring

an action under ERISA section 502(a);

- upon request and free of charge, a copy of any internal rule, guideline, protocol or other similar criterion that was relied upon in making the adverse determination regarding your appeal, and an explanation of the scientific or clinical judgment for a determination that is based on a Medical Necessity, experimental treatment or other similar exclusion or limit; and
- information about any office of health insurance consumer assistance or ombudsman available to assist you in the appeal process. A final notice of adverse determination will include a discussion of the decision.
- a statement regarding the availability of language assistance services.

An adverse determination will also inform you of the following: “We have denied your request for the provision of or payment for a health care service or course of treatment. You may have the right to have our decision reviewed by health care professionals who have no association with us if our decision involved making a judgment as to the Medical Necessity, appropriateness, health care setting, level of care, or effectiveness of the health care service or treatment you requested by submitting a request for external review to the Commission.” You also have the right to bring a civil action under Section 502(a) of ERISA if you are not satisfied with the decision on review. You or your plan may have other voluntary alternative dispute resolution options such as Mediation. One way to find out what may be available is to contact your local U.S. Department of Labor office and your State insurance regulatory agency. You may also contact the Plan Administrator.⁵

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 requirement 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
M.C. Dean, Inc. 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.
Commercial 3 Tier MED SURG By Formulary	This document reflects the M/S formularies including which drugs require prior authorization.
Commercial 3 Tier MH SUD 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 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	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 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

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, 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	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, information provided from pharmaceutical manufacturers, the FDA, and information gleaned from external clinical bodies and industry groups
---	---

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.	
Step Therapy: 1. Availability: The availability of medical or pharmacy medications (products) depends upon two market conditions (1) the market 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	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. 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

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 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.	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 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 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.	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) 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
---	---

In the development of the 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: 1. Risk of adverse safety issues 2. Specialty drug status 3. Inappropriate utilization 4. Clinical safety and efficacy 5. Clinical guidelines and standards	Prior Authorization: 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.	Prior Authorization: 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.

	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 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 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 (cigna.com)

	• 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. 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	• 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 Distinguishing Effectiveness From Efficacy Trials in Systematic Reviews - NCBI Bookshelf
--	---	---

	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 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	(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.
--	---	--

	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) 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/ 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 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:	Quantity Limits:	Quantity Limits:

1. Risk of adverse safety issues 2. Clinical safety and efficacy	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, 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 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	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
---	---	--

	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.	
--	--	--

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) [\[Note that this applies to Step 3 in the context of committees/experts that design the NQTL, such as a Pharmacy & Therapeutics Committee or Prior Authorization Committee\]](#).
- (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 [\[Note that this is asking the issuer to explain/justify any differences between MH/SUD benefits and M/S benefits and to explain why the differences are not more restrictive for MH/SUD benefits\]](#):
 - (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) [Note that this applies to Step 4 in the context of the processes used to apply the NQTL, such as first-level review, second-level review, and peer-to-peer review].
- (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 a 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 Cotelpla 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	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	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

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	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): - sumatriptan injectable P - 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 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	- 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.
---	---	--

ST			
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/flu- vastatin 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	

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
RELEXII	NURTEC ODT
RITALIN LA	ONZETRA XSAIL
STRATTERA	QDOLO
XELSTRYM	QULIPTA
VYVANSE	RELPAK
	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 large group 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 its group 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 (across all formularies 5.0% or less of MH/SUD and 11.04% or less of M/S drug NDCs each are covered off-formulary). Second, a comparable, and, in fact, lower, percentage of MH/SUD drug NDCs are covered on the higher cost, non-preferred brand tier (Tier 3) of the group formularies offered by Cigna as compared to the MH/SUD drug NDCs covered on Tiers 1 and 2.

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.

Advantage 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	12,030		66,548	
On Formulary	11,400	94.76%	61,033	91.71%
Non-Formulary	630	5.24%	5,515	8.29%
Tier 1 Drugs	11,224	93.30%	57,147	85.87%
Tier 2 Drugs	62	0.52%	1,470	2.21%
Tier 3 Drugs	744	6.18%	7,661	11.51%
Drugs requiring Prior Auth	1096	9.76%	6,793	11.89%
Drugs requiring Step Therapy	83	0.74%	270	0.47%
Drugs requiring Quantity Limits	4033	35.93%	7,710	13.49%
Legacy 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,465	
On Formulary	11,598	99.21%	55,654	96.85%
Non-Formulary	92	0.79%	1,811	3.15%
Tier 1 Drugs	10,975	93.88%	50,860	88.51%
Tier 2 Drugs	34	0.29%	1,942	3.38%
Tier 3 Drugs	681	5.83%	4,843	8.43%
Drugs requiring Prior Auth	1,578	14.38%	8,339	16.40%
Drugs requiring Step Therapy	167	1.52%	397	0.78%
Drugs requiring Quantity Limits	3,962	36.10%	7,770	15.28%
Legacy Performance 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	12,030		66,946	
On Formulary	12,024	99.95%	66,824	99.82%
Non-Formulary	6	0.05%	122	0.18%
Tier 1 Drugs	11,224	93.03%	57,747	86.26%
Tier 2 Drugs	67	0.56%	1,703	2.54%

Tier 3 Drugs	739	6.14%	7,496	11.20%
Drugs requiring Prior Auth	1,600	13.30%	10,085	17.46%
Drugs requiring Step Therapy	167	1.39%	397	0.69%
Drugs requiring Quantity Limits	4,033	33.52%	7,755	13.43%
Performance 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	12,030		66,946	
On Formulary	11,522	95.78%	63,242	94.47%
Non-Formulary	508	4.22%	3,704	5.53%
Tier 1 Drugs	11,224	93.30%	57,747	86.26%
Tier 2 Drugs	61	0.51%	1,666	2.49%
Tier 3 Drugs	745	6.19%	7,533	11.25%
Drugs requiring Prior Auth	1,126	10.03%	6,758	11.70%
Drugs requiring Step Therapy	69	0.61%	318	0.48%
Drugs requiring Quantity Limits	4,033	35.93%	7,755	13.43%
Standard 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,645	
On Formulary	11,112	95.06%	52,340	90.80%
Non-Formulary	578	4.94%	5,305	9.20%
Tier 1 Drugs	10,975	93.88%	50,860	88.23%
Tier 2 Drugs	28	0.24%	1,897	3.29%
Tier 3 Drugs	687	5.88%	4,888	8.48%
Drugs requiring Prior Auth	1,120	10.21%	5,089	10.01%
Drugs requiring Step Therapy	69	0.63%	319	0.63%
Drugs requiring Quantity Limits	3,980	36.26%	7,770	15.28%
Value 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,350	
On Formulary	11,076	94.75%	50,852	88.67%
Non-Formulary	614	5.25%	6,498	11.33%
Tier 1 Drugs	10,975	93.88%	50,619	88.26%
Tier 2 Drugs	30	0.26%	1,729	3.01%
Tier 3 Drugs	685	5.86%	5,002	8.72%
Drugs requiring Prior Auth	1,090	9.93%	5,126	10.13%

Drugs requiring Step Therapy	83	0.76%	270	0.53%
Drugs requiring Quantity Limits	3,962	36.10%	7,725	15.26%

Across all formularies, a lower percentage of MH/SUD drugs require prior authorization or step therapy as compared to M/S. 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.

While operational outcomes are not determinative of NQTL compliance, an insurer may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement. Consequently, the comparable outcomes in the incidence rates of on versus non-formulary and drugs on preferred tiers for MH/SUD and M/S drugs offers evidence that Cigna's formulary/placement and tiering practices, in-operation, are comparable and applied no more stringently to MH/SUD drugs.

As far as methodology applicable to the Commercial 3 Tier, Cigna filters out the following products to be included in MH based on their General Therapeutic Category (GTC)

- Autonomic Drugs: Adrenergic, Aromatic, Non-Catecholamine
- Anti-Anxiety
- Antidepressants
- Antipsychotic
- Bipolar Disorder Drugs
- MOA Inhibitors
- Narcolepsy and Sleep Disorders
- Treatments for ADHD
- Smoking Deterrents

For SUD, Cigna filters out the following products to be included based on their General Therapeutic Category (GTC)

- Analgesics: Opioid Analgesics
- Antidotes: Opioid Antagonists
- Anti-alcoholic Preparations
- Opioid Withdrawal Therapy Agents

For M/S Drugs, the drug list shall consist of all drugs in the Book of Record excluding:

- All benefit excluded drugs
- Any drug on MH/SUD list
- Topical Hemostatics
- Medical Supplies
- General Anesthetics

Methodology to determine calculations on the Rx Summary:

Tier 1 = generic	Tier 2 = preferred	Tier 3 = on formulary non
------------------	--------------------	---------------------------

		preferred brands
N= new drug	X = benefit excluded, not covered	Y= Exclusion not covered unless meet med nec criteria

Tiers 1 and 2 - X, Y, and Z are exclusions; these exclusions were used to determine on vs. non-formulary. The data column is named "excluded" but these are non-formulary, not benefit excluded. Generally, non-formulary drugs always have a path to approval for medical necessity. Generally, benefit exclusions do not have a path to approval. The rationale is that non-formulary drugs could be medically necessary. Benefit excluded drugs are considered optional and not medically necessary.

For Tier 3 - N is for new drugs normally placed on Tier 3 and were included in the on-formulary calculations.

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 MH/SUD Commercial 3 Tier and select any package tab, Adv3 T, sort column "O" for "1" which is Tier 1 and filter column "P" for exclusions "X" this will provide the total on formulary for Advantage 3. That process is repeated for all tabs 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).

Commercial 3 Tier Design

Column N = Tier Type filter to determine results by tier	Column O = Excluded column is used to determine on vs non-formulary	Column P = 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
---	---	--

Commercial 3 Tier Tabs

ADV3T= Advantage 3 Tier	STD3T= Standard 3 Tier	PRF3T= Performance 3 Tier	VAL3T= Value 3 Tier	LEG3T= Legacy 3 Tier or Legacy Standard	LPR3T= Legacy Performance 3 Tier	TS AON= Total Savings
-------------------------------	------------------------------	---------------------------------	---------------------------	---	---	--------------------------

Cigna is providing the Virginia and commercial book of business pharmacy utilization management results below. The source of the data is the Cigna C360 UM Management system.

2025 Virginia 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	968		18,718	
Total Number of Pharmacy Authorization Requests Denied	436	45.04%	6,055	32.35%
Total Number of Pharmacy Authorization	532	54.96%	12,663	67.65%

Requests Approved				
Total Number of Pharmacy PA requests Received	262		12,950	
Total Number of Pharmacy PA requests Denied	131	50.00%	3,415	26.37%
Total Number of Pharmacy PA Approved	131	50.00%	9,535	73.63%
Total Number of Step-Therapy or Fail-First Requests Received	136		562	
Total Number of Step-Therapy or Fail-First Requests Denied	27	19.85%	36	6.41%
Total Number of Step-Therapy or Fail-First Requests Approved	109	80.15%	526	93.59%
Total Number of QL Requests Received	112		1131	
Total Number of QL requests Denied	22	19.64%	400	35.37%
Total Number of QL requests Approved	90	80.36%	731	64.63%
Total Number of DRT/NonFormulary Requests Received	458		4,075	
Total Number of DRT/NonFormulary Requests Denied	256	55.90%	2,204	54.09%
Total Number of DRT/NonFormulary Requests Approved	202	44.10%	1,871	45.91%
Total Number of On Formulary Requests Received	510		14,643	
Total Number of On Formulary Requests Denied	180	35.29%	3,851	26.30%
Total Number of On Formulary Requests Approved	330	64.71%	10,792	73.70%

The 2025 Virginia pharmacy utilization management data reflects substantially different volumes between MH/SUD and M/S benefits, with 968 total MH/SUD requests compared with 18,718 M/S requests. Accordingly, percentage differences should be considered in the context of the underlying volumes, as individual determinations have a greater effect on rates within the smaller MH/SUD population. While MH/SUD had a higher volume of prior authorization and step therapy denials, the quantity limit denials were lower and the nonformulary denials were comparable.

The outcome differences should be evaluated together with the substantially different request volumes and the documented use of the same factors, evidentiary standards, review processes, and exception pathways for MH/SUD and M/S drugs when assessing comparability and relative stringency.

2025 Cigna 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	63,794		1,184,709	
Total Number of Pharmacy Authorization Requests Denied	25,232	39.55%	355,602	30.02%
Total Number of Pharmacy Authorization Requests Approved	38,562	60.45%	829,107	69.98%
Total Number of Pharmacy PA requests Received	18,025		772,029	

Total Number of Pharmacy PA requests Denied	6,203	34.41%	194,373	25.18%
Total Number of Pharmacy PA Approved	11,822	65.59%	577,656	74.82%
Total Number of Step-Therapy or Fail-First Requests Received	10,588		101,672	
Total Number of Step-Therapy or Fail-First Requests Denied	2,002	18.91%	13,061	12.85%
Total Number of Step-Therapy or Fail-First Requests Approved	8,586	81.09%	88,611	87.15%
Total Number of QL Requests Received	6,324		64,005	
Total Number of QL requests Denied	1,042	16.48%	23,290	36.39%
Total Number of QL requests Approved	5,282	83.52%	40,715	63.61%
Total Number of DRT/NonFormulary Requests Received	28,857		247,003	
Total Number of DRT/NonFormulary Requests Denied	15,985	55.39%	124,878	50.56%
Total Number of DRT/NonFormulary Requests Approved	12,872	44.61%	122,125	49.44%
Total Number of On Formulary Requests Received	34,937		937,706	
Total Number of On Formulary Requests Denied	9,247	26.47%	230,724	24.61%
Total Number of On Formulary Requests Approved	25,690	73.53%	706,982	75.39%

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 commercial book of business data, MH/SUD had an overall higher denial percentage when compared to M/S (39.55% and 30.02% respectively). The higher denial percentage is primarily attributable to prior authorization and step therapy.

The primary drug types driving the higher MH/SUD prior authorization denial percentage are ADHD and wakefulness promoting agents. ADHD drugs are Schedule II controlled substances that have a high potential for abuse, misuse, and diversion and therefore require a higher level of clinical review. Also, several of the ADHD medications have generic formulations available and there must be supporting documentation provided to show a contraindication to the covered alternative generic. For the wakefulness promoting agents, these are Schedule IV controlled substances which have high potential for abuse, misuse, or diversion. Furthermore, there are three approved FDA indications (narcolepsy, obstructive sleep apnea, shift work disorder). In addition to these FDA approved indications, there are certain off-label uses supported by the American Psychiatric Association and the American Academy of Sleep Medicine which may be covered for members. These off-label uses require documentation from the provider to fulfill coverage requirements. If providers do not supply the required documentation, the request is denied. As with the ADHD medications, the denials seen in the data are initial determinations only and not the final decision.

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 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