

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.

Pharmacy Formulary Design

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:

Pharmacy Formulary is 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 Pharmacy Formulary 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 Pharmacy Formulary 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 Pharmacy Formulary NQTL, Cigna reviewed summary plan documents, benefit descriptions, and 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 Pharmacy Formulary is excerpted from the M.C. Dean, Inc. plan certificate and states as follows:

M.C. Dean, Inc. Plan Language
Prescription Drug Benefits Covered Expenses Your plan provides benefits for Prescription Drug Products dispensed by a Pharmacy. Details regarding your plan’s Covered Expenses, which for the purposes of the Prescription Drug Benefit include Medically Necessary Prescription Drug Products ordered by a Physician, Limitations, and Exclusions are provided below and/or are shown in The Schedule. Your prescription drug benefits will not be denied for any drug approved by the United States Food and Drug Administration for use in the treatment of cancer pain, on the basis that the dosage is in excess of the recommended dosage of the pain-relieving agent, if the prescription has been prescribed for intractable cancer pain. If you or any one of your Dependents, while insured for Prescription Drug Benefits, incurs expenses for charges made by a Pharmacy for Medically Necessary Prescription Drug Products ordered by a Physician, your plan provides coverage for those expenses as shown in The Schedule. Your benefits may vary depending on which of the Prescription Drug List tiers the Prescription Drug Product is listed, or the Pharmacy that provides the Prescription Drug Product. Coverage under your plan’s Prescription Drug Benefits also includes Medically Necessary Prescription Drug Products dispensed pursuant to a Prescription Order or Refill issued to you or your Dependents by a licensed dentist for the prevention of infection or pain in conjunction with a dental procedure. When you or a Dependent are issued a Prescription Order or Refill for Medically Necessary Prescription Drug Products as part of the rendering of Emergency Services and Cigna determines that it cannot reasonably be filled by a Network Pharmacy, the prescription will be covered pursuant to the, as applicable, Copayment or Coinsurance for the Prescription Drug Product when dispensed by a Network Pharmacy. Prescription Drug List Management Your plan’s Prescription Drug List coverage tiers may contain Prescription Drug Products that are Generic Drugs, Brand Drugs or Specialty Prescription Drug Products. Determination of inclusion of a Prescription Drug Product to a certain coverage tier on the Prescription Drug List and utilization management requirements or other coverage conditions are based on a number of factors which may include, clinical and economic factors. Clinical

factors may include, but are not limited to, the P&T Committee's evaluations of the place in therapy, relative safety or relative efficacy of the Prescription Drug Product, as well as whether certain supply limits or other utilization management requirements should apply. Economic factors may include, but are not limited to, the Prescription Drug Product's acquisition cost including, but not limited to, assessments on the cost effectiveness of the Prescription Drug Product and available rebates. Regardless of its eligibility for coverage under the plan, whether a particular Prescription Drug Product is appropriate for you or any of your Dependents is a determination that is made by you or your Dependent and the prescribing Physician.

The coverage status of a Prescription Drug Product may change periodically for various reasons. For example, a Prescription Drug Product may be removed from the market, a New Prescription Drug Product in the same therapeutic class as a Prescription Drug Product may become available, or other market events may occur. Market events that may affect the coverage status of a Prescription Drug Product include, but are not limited to, an increase in the acquisition cost of a Prescription Drug Product. As a result of coverage changes, for the purposes of benefits the plan may require you to pay more or less for that Prescription Drug Product, to obtain the Prescription Drug Product from a certain Pharmacy(ies) for coverage, or try another covered Prescription Drug Product(s). Please access the Prescription Drug List through the website shown on your ID card or call member services at the telephone number on your ID card for the most up-to-date tier status, utilization management, or other coverage limitations for a Prescription Drug Product.

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

Glossary:

1. **Benefit Exclusion:** means a provision of a benefit plan that excludes coverage for a drug regardless of whether the drug is "medically necessary" to treat a particular indication. For example, a benefit plan may exclude coverage for over-the-counter drugs 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. 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.
6. Industry Codeset Committee ("Industry Codeset"): is a chartered subcommittee of the HVAC accountable for making initial decisions related to drug coverage under Cigna Healthcare's commercial group and individual products based on changes to the drug supply, as reflected in third-party databases or other general market conditions, according to HVAC and P&T Committee policies.
7. Negative Prescription Drug List change: is any movement of a drug to a higher cost-share tier, the removal of a drug from the Prescription Drug List (except for the movement of a drug to a higher cost-share tier on, or of a UM requirement to a drug, or the exclusion of a previously covered drug from coverage.
8. New Molecular Entities ("NME"): means that a drug's active ingredient has not been previously approved for marketing by the FDA and is not a version or derivative of an existing and previously FDA-approved substance.
9. New-to-Market drug: means that a drug product approved to marketing by the FDA has recently become commercially available for customers to purchase.
10. Pharmacy and Therapeutics ("P&T") Committee: 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.
11. Positive Prescription Drug List change: is any movement of a drug to a lower cost-share tier, the addition of a drug to the Prescription Drug List, or removal of a UM requirement on a drug.
12. Prescription Drug List: means a list offered as part of group and/or individual health plans that categorizes drug products that have been approved by the U.S Food and Drug Administration ("FDA") into coverage tiers. The list is developed and maintained by Cigna Healthcare's Value Assessment Committee ("HVAC"), based on clinical findings communicated by the Pharmacy & Therapeutics ("P&T") Committee.
12. Utilization Management ("UM") requirements: mean methods by which a health plan or PBM manage coverage for drugs. UM requirement may include, but are not limited to, Sleep Therapy, Prior Authorization, Quantity Limits, and Age Limits.
 - 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.
 - 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.
 - 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
PT Comm PP Final	This document outlines the process by which the National Pharmacy and Therapeutics (P&T) Committee reviews and approves national formularies.

Cigna maps benefit classifications for MH/SUD and M/S benefits consistent with generally recognized independent standards of medical practice. Those classifications include:

Is NQTL applied to Prescription classification?	Is NQTL applied to Inpatient classification?	Is NQTL applied to Outpatient- Office sub-classification?	Is NQTL applied to Outpatient-All Other sub-classification?	Is NQTL applied to Emergency classification?
YES - Includes both M/S and MH/SUD	NO - for both M/S and MH/SUD	NO - for both M/S and MH/SUD	NO - for both M/S and MH/SUD	NO - for both M/S and MH/SUD

List of Services Subject to the NQTL:

- The supporting documentation titled Commercial 3 Tier MH SUD by Formulary column Q and Commercial 3 Tier MS by Formulary column P will identify PA, ST, and QL if applicable for medications.

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:

Cigna offers several formularies comprised of generic, preferred, and non-preferred brand name drugs, and specialty drugs which are addressed in this analysis. Requirements designing formulary are developed without regard to whether the prescription drugs are prescribed to treat a medical/surgical (M/S) condition, or a mental health/substance use disorder (MH/SUD) condition.

The NQTL requirement provides that a NQTL applied to MH/SUD benefits, including prescription drug benefits, be designed and administered such that, as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in the prescription drug classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in applying the NQTL with respect to M/S benefits in the classification and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits.

In designing and applying the prescription drug formulary, Cigna relies on reasonable factors that are applied comparably to both MH/SUD and M/S benefits, consistent with MHPAES requirements. These factors include clinical considerations e.g., safety and efficacy as evaluated by Pharmacy & Therapeutics committee (P&T) and non-clinical considerations e.g., brand versus generic status and economic value as assessed by Healthcare Value Assessment Committee (HVAC).

The coverage of drugs on Cigna’s formularies is, subject to a client policyholder’s election determined by two internal/ affiliated committees that perform different but interrelated functions: the Pharmacy & Therapeutics Committee (“P&T Committee”) and the Cigna Healthcare Value Assessment Committee (“HVAC”).

The P&T Committee, who is responsible for clinical factors (e.g., clinical safety and efficacy) is composed of voting external clinicians across a number of specialties 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. The sources for the clinical practice standards, trends, and documentation such as clinical literature and guidelines are accredited medical and pharmacy organizations (i.e., American Medical Association, American Pharmacists Association) and federal agencies (i.e., FDA or CDC).

The HVAC, who is responsible for non-clinical factors (e.g., status of drug and economic value) is composed of individuals representing several functional areas of the combined company, including for example, clinicians and representatives from Cigna’s sales and economics areas that have experience with formulary management or PBM/health plan operations. The HVAC 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. If the P&T Committee finds that a drug must be covered on the formulary as a clinical matter, then the HVAC must place the drug on the formulary. If the P&T Committee determines that a drug may or may not be covered on the formulary as a clinical matter, then the HVAC may consider other factors, including economic factors, in deciding whether to place the drug on the formulary.

In its decision criteria, the P&T and Cigna HVAC consider the following factors. There were no additional factors considered and rejected. These factors are applied uniformly and do not operate in a systematically discriminatory manner, as they are not based on data, sources, or evidence that disfavor MH/SUD, including outdated, non-objective, or biased medical guidelines.

Factor	Definition
1. Pharmacy and Therapeutics (“P&T”) Committee clinical safety and efficacy evaluation and designation.	1. 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 clinical evidence-based determination relative to safety and efficacy of a drug by the P&T committee summarizes the current medical knowledge, weigh the benefits and harms of diagnostic procedures and treatments.
2. Economic implications to	2. Economic implications to clients, customers (i.e., individual participants or members) and Cigna, or the relevant Cigna entity to the extent that Cigna is

enrollees and Cigna	contractually responsible to clients or members for claims expenditures.
3. Status of drug as a generic, brand, or specialty drug	3. Generic drugs are approved by the FDA as having the same active ingredient as the brand-name drug. Generally, generic drugs cost less than brand-name drugs. Specialty medications are used to treat complex medical conditions. Brand and Generic drug status is determined by algorithm utilizing published data attributes provided by First Databank. The brand generic algorithm has a hierarchical determination process. Specialty drug status, specialty drugs can be given by any route of administration, are typically used to treat chronic, complex conditions, and are defined as having one or more of several key characteristics, including: 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; specialized product handling and or administration requirements. Limited specialty pharmacy distribution: A drug is considered limited distribution if it meets one of the following circumstances: Limited Large – The manufacturer has contractually designated six (6) or more national/regional specialty pharmacies to order/stock/dispense a pharmaceutical product. No retail dispense. Limited Small - The manufacturer has contractually designated between two (2) and five (5) specialty pharmacies to order/stock/dispense a pharmaceutical product. No retail dispense. Exclusive – A single specialty pharmacy is designated to order/stock/dispense a pharmaceutical product. • Frequent dosing adjustments means more frequent than every 30 days. • Intensive clinical monitoring means when clinicians on the Specialty Drug List Workgroup and the Specialty Advisory Board are reviewing medications to determine if they require intensive clinical monitoring, we use our subjective clinical judgement. We assess the known safety risks and determine if they are milder/easily managed or more severe and require more intensive monitoring. Intensive patient training means when clinicians on the Specialty Drug List Workgroup and the Specialty Advisory Board are reviewing medications to determine if they require intensive patient training, it is less subjective. The primary reason a drug would meet this criterion would be if patient or caregiver training is required to self-administer an injection.
4. Competitor/ market practices	4. This factor refers to an assessment of how competitors are covering drugs on their formularies based on publicly available information, which, while never determinative, may be considered when making certain formulary decisions. Competitor/market practices includes a pharmacoeconomic review which utilizes cost benefit analysis and cost effectiveness analysis to evaluate the value of an intervention within a population or to evaluate the costs and health effects of a specific intervention. This definition also includes business and market considerations, as relevant for particular lines of business.

5. Legal and regulatory requirements	5. Any legal or regulatory requirements that mandate certain drug coverage, such as tier placement requirements.
6. Operational feasibility	6. Operational feasibility is the measure of how well a proposed system solves problems and takes advantage of the opportunities identified during scope definition and how it satisfies the requirements identified in the requirements analysis phase of system development.
7. Provider impact	7. Drug product availability from pharmacy/distributor. Cigna completes an operational assessment through our Vision & Value meetings that ask our SME partners to provide feedback on how a strategy would be implemented. From a provider impact perspective Cigna must ensure that our providers can adequately carry out a strategy. An example of this would be ensuring a provider would have access to a drug that would need to be administered in an office setting. In terms of factors given more weight, Drugs with a designation of include are recommended for placement on all formularies. A drug may be given an include designation if it meets at least one of the clinical basis is anticipated via claims data, to treat a relatively large patient population. The clinical basis includes unique indication for use addressing a clinically significant unmet treatment need, efficacy superior to that of existing therapy alternatives, a safety profile superior to that of existing therapy alternatives, a unique place in therapy, and/or drugs which treat medical conditions that necessitate individualized therapy and for which there are multiple treatment options.

Below are the **evidentiary standards** Cigna uses to determine the formulary

Factors	Evidentiary Standards and Applicable Thresholds	Source(s) for Each Evidentiary Standard
1. Pharmacy and Therapeutics ("P&T") Committee Clinical safety and efficacy evaluation and designation	1. Pharmacy and Therapeutics ("P&T") Committee clinical safety and efficacy evaluation and designation: The clinical P&T Committee's designations are based on reviews of a drug's safety and efficacy and place in therapy, using available clinical evidence such as FDA label information and available clinical literature and guidelines (e.g. federal regulatory publications or professional society publications). 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 dictate 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	1. Pharmacy and Therapeutics ("P&T") Committee clinical safety and efficacy evaluation and designation: 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), Applying a Subpopulation Lens to Population Health NEJM, An approach to addressing subpopulation considerations in systematic reviews: the experience of reviewers supporting the U.S. Preventive Services Task Force - PMC (nih.gov) 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. The sources for determining that the drug is similar in terms of safety and efficacy to other currently available drug alternatives

	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 as follows: Include: A drug may be given an include designation if it meets at least one of the clinical basis enumerated below and is anticipated claims data, to treat relatively large patient population (i.e., greater than 1 in 50,000). The clinical basis include: It has a unique indication for use addressing a clinically significant unmet treatment need, Its efficacy is superior to that of existing therapy alternatives, Its safety profile is superior to that of existing therapy alternatives, it has a unique place in therapy; and/or It treats medical condition(s) that necessitate individualized therapy and for which there are multiple treatment options. 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 possess the same mechanism of action and a similar place in therapy. <u>Definitions:</u> A unique indication for use 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 drugs clinical outcomes surpass other drugs for the same indications. Efficacy is based on clinical studies involved in a drugs approval which is admitted by the FDA	include: The FDA’s Drug Review Process, NIH, and AAFP. Ensuring Drugs Are Safe and Effective https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective 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 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 clinical trials.
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	A medication that is determined to have inferior efficacy over others, may not necessarily result in an Exclude parameter. Inferior efficacy may be ascertained by evaluating the data clinical trials, ideally looking at direct comparative studies, and if not available, evaluating the data available and, if appropriate, comparing it to the data available for therapeutic alternatives and/or insufficient data to evaluate the drug. 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. <u>Definition:</u> • Clinically Significant: practical importance or meaningfulness of a treatment effect or study result in relation to a patient's well-being or health • Superior: the term “clinically superior” with respect to a drug means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care. As part of the review process, the place in therapy of a new medication is considered relative to the similar medications that treat the same condition(s). These evaluations are made by looking at the clinical trial data available. Ideally superior efficacy is determined by a head-to-head direct comparative study, which may or may not be available at the time of a new drug review for an FDA approved medication. With that said, during the evaluation process, there may be some indirect comparisons with therapeutic alternatives considered and evaluated from similarly designed clinical trials. The types of data we have to evaluate are not uniform across drug reviews. In the context of the Include definition and using the phrase “superior”, it may or	
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	may not be from a direct trial, but may be an evaluation of the totality of the available data from the P&T Committee. • 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), Applying a Subpopulation Lens to Population Health NEJM, An approach to addressing subpopulation considerations in systematic reviews: the experience of reviewers supporting the U.S. Preventive Services Task Force - PMC (nih.gov) The clinical basis include: • It has a unique indication for use addressing a clinically significant unmet treatment need; • Its efficacy is superior to that of existing therapy alternatives; • Its safety profile is superior to that of existing therapy alternatives; • It has a unique place in therapy; and/or • It treats medical condition(s) that necessitate individualized therapy and for which there are multiple treatment options. Access drugs are forwarded to the Healthcare Value Assessment Committee for further analysis of whether the drug should be covered on the applicable formulary and, if covered on the formulary, on which tier. The Healthcare Value Assessment Committee may either place the drug on the applicable formulary or designate the drug as non-formulary. Access must be provided by placement of the drug on the formulary or consistent with the formulary exception criteria defined by the P&T Committee. If the	
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	Healthcare Value Assessment Committee does not place the drug on the formulary, the P&T Committee shall establish formulary exception clinical criteria. The formulary exception clinical criteria are guidelines set by the P&T Committee for what they will allow to be placed on formulary. When performing a formulary strategy, if a plan or Pharmacy Benefit Manager is conducting a tier placement of a new drug, the formulary exception criteria provide P&T's guidelines for what they will allow. The guidelines are used internally by the formulary team when bringing forth a strategy for a certain drug class. 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. In certain instances, an optional drug may have a unique use in a relatively small subset of patients (small in relation to the overall use of the medicine). 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 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 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 https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective Overview of methods for comparing the	
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	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 clinical trials.	
2. Economic implications to enrollees and Cigna	2. Economic implications to enrollees and Cigna: When assessing potential formulary placement decisions, the Cigna HVAC reviews based on projected drug expenditure information derived from available manufacturer revenue and claims costs whether a drug is a lower net cost option relative to any therapeutic alternatives. If a brand drug does not have generic equivalents/alternatives and is a lower net cost option than alternative brand drugs with equivalent or lesser P&T Committee clinical designations, or Cigna has a rebate arrangement in place for a brand drug, then Cigna generally places a brand drug on the preferred brand tier (i.e., Tier 2) of the formularies. When it comes to egregious pricing, Cigna would decline placing a drug at Tier 2 for egregious pricing. There are no drugs for	2. Economic implications to enrollees and Cigna: Sources include available manufacturer revenue and claims costs.

	MS or MH/SUD that did not get assigned to Tier 2 because there are none for MS and MH/SUD.	
3. Status of drug as a generic, brand, or specialty drug	3. Status of drug as a generic, brand, or specialty drug: A drug is identified as generic, or brand based on an algorithm that considers drug indicators made available by an external vendor called First DataBank. A drug is identified as a specialty drug based on the presence of one more of the following characteristics as determined by 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. Cigna offers several formularies for its large group insured business. For most formularies, some drugs are not covered on any formulary tier; these drugs may be referred to as "non-formulary" drugs. A drug may be designated as non-formulary or excluded for one of several possible reasons, whether it is an M/S or MH/SUD benefit. A drug may be designated as non-formulary because it is excluded from coverage by the benefit plan irrespective of medical necessity (e.g. the drug is not FDA-approved, or prescribed to treat a condition not covered by the benefit plan), or because the applicable formulary committee(s) determine after consideration of several clinical and non-clinical factors that it doesn't warrant coverage on the formulary or, for individual	3. Status of drug as a generic, brand, or specialty drug: Sources include clinical evidence like FDA product labeling, clinical literature and guidelines claims/reimbursement information and available manufacturer revenue, and First DataBank's drug indicator file.

	formularies, is not required by law to be covered on the formulary. If the P&T Committee identifies a brand drug as “Include,” then it is placed on the formulary and covered in a manner no less preferential than alternative brand drugs in the same class. If the P&T Committee identifies a drug as “Exclude” or “Optional,” then the Cigna HVAC may designate the drug as non-formulary if it covers on the formulary a preferred covered alternative that is lower net cost option (inclusive of ingredient cost as sourced from claims/reimbursement information and available manufacturer revenue) to Cigna as compared to therapeutic alternatives. For large group insured plans, Tier 1 includes formulary generic drugs. Tier 2 includes formulary preferred brand drugs. Tier 3 includes formulary non-preferred brand drugs. The brand or generic status of a drug is determined by reference to an algorithm that analyzes available drug indicators, currently including First DataBank’s drug indicator file, and not by reference to the drug’s status as an M/S or MH/SUD benefit. Once brand drug status is determined by application of the algorithm, a covered brand drug is typically placed on Tier 2 for one of several reasons, including if the drug lacks available generic alternatives, or if Cigna maintains a rebate arrangement for the brand drug such that the drug is a lower cost alternative as compared to other brand drugs. Upon market entry, all formulary brand drugs are placed on Tier 3, unless placement on Tier 2 is warranted based on whether Cigna has any manufacturer revenue arrangements, or the drug is otherwise the low net cost option as compared to alternative drugs. Tier 4, if elected by the client plan sponsor, includes specialty drugs identified based on application of the above-stated definition.	
4. Competitor/ market practices	4. Competitor/market practices: This factor refers to an assessment of how competitors are covering drugs on their formularies based on publicly available information, which, while never determinative, may be considered when making certain formulary decisions.	4. Competitor/market practices: Sources include competitors covering of drugs on their formularies based on publicly available information.

5. Legal and regulatory requirements	5. Legal and regulatory requirements: This factor refers to any legal or regulatory requirements that mandate certain drug coverage, such as tier placement requirements.	5. Legal and regulatory requirements
6. Operational feasibility	6. Operational feasibility: This factor Operational feasibility is the measure of how well a proposed system solves problems and takes advantage of the opportunities identified during scope definition and how it satisfies the requirements identified in the requirements analysis phase of system development.	6. Operational feasibility
7. Provider impact	7. Provider impact: This factor refers to drug product availability from pharmacy/distributor.	7. Provider impact

Regarding weighting, the factor that is given more weight is clinical safety and efficacy. Safety data comes from the product's package insert, which sites clinical studies used in the approval process.

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 Factors

Methods and practices used to design the formulary are as follows:

Clinical factors are assessed by the P&T Committee to evaluate the safety and efficacy of drugs and based on that evaluation, assign one of several designations to each drug: Include Access; Optional; or Exclude.

Pharmacy and Therapeutic Committee

The Pharmacy and Therapeutic Committee (P&T) consists of independent (external) physicians and pharmacists from active community and academic-based practices representing a broad range of medical specialties. The P&T Committee members are selected based on contributions to the medical and pharmacy literature; national recognition in their specialty; involvement in clinical (patient care) practice (membership prerequisite) and previous experience with P&T committees. The Committee is chaired by an elected member.

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 specialty. They are responsible for clinical reviews of drugs to determine whether a drug must be covered on the formulary as a clinical matter. The P&T Committee reviews a broad range of formulary placement topics. As noted in step two, the P&T Committee assesses the FDA labeling and, as appropriate and available, clinical practice standards/trends and documentation like clinical literature and guidelines. The sources for the clinical practice standards, trends, and documentation such as clinical literature and guidelines are accredited medical and pharmacy organizations, for example, American Medical Association, American Pharmacists Association) and the FDA or CDC.

The P&T Committee reviews medications based purely on a clinical perspective. The Committee does not have access to, nor does it consider, any information regarding Cigna's rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The Committee does not use price, in any way, to make formulary placement decisions.

The P&T committee meets six times per year. Packets of materials are distributed to P&T members. These materials may include, but are not limited to, new drug evaluations, place in therapy documents, clinical product category (CPC) comparisons, a listing of medications that received new FDA-approved indications, new clinical line extensions, and any other clinical materials that may facilitate resolution of clinical issues. Drugs reviewed will have received FDA final approval and labeling.

After review of the information and discussion among P&T members, the Committee will vote if the drug should be given the status of Include, Access, Optional, or Exclude on the formulary. The committee must base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, outcomes research data, and incorporating their own clinical practice experiences. Financial information will be neither discussed nor impact the committee's clinical decisions. Reasonable effort will be made to review drugs within 90 days of release onto the market in the U.S., and decisions will be made within 180 days of introduction to the marketplace.

Drugs deemed to be Include will be added to all National Formularies. Drugs deemed to be Exclude will not be added to any National Formularies. Drugs defined as Optional or Access by the P&T Committee shall be forwarded to the HVAC for financial consideration. Subject to the P&T Committee's periodic review, the HVAC shall make the final formulary determination for Optional and Access medications (adhering to any P&T Committee therapy class-specific clinical parameters). The P&T Committee shall review all final decisions, at least annually, when they formally review and approve the National Formularies (Commercial).

Clinical programs or issues referred for consultation from clinical committees will be reviewed by appropriate P&T Committee physicians as determined by the Senior Director, Institute of Clinical Oversight and Guidance(ICOG) and Chairman. Input from non-P&T Committee experts may be obtained occasionally and will be shared with the appropriate P&T Committee member(s).

On an annual basis, the P&T Committee will review the final formulary recommendations, by drug class, for the upcoming plan year and:

- approve existing clinical parameters and HVAC guidelines.

- review all policies and procedures relating to formulary/utilization management programs. The Committee will vote for approval of any required changes.
- approve inclusions or exclusions of therapy classes National Formularies

The Committee also uses this opportunity to ensure adherence to previously established formulary placement recommendations, and to validate continued alignment with best medical practices. The Committee also ensures that all Cigna national formularies cover a broad distribution of therapeutic classes and categories, and that the formularies neither discourage enrollment by any group of enrollees nor discriminate against certain patient populations.

On a monthly basis, Cigna's Institute of Clinical Oversight & Guidance staff will review the Office of Inspector General (OIG) and GSA exclusion lists to ensure that no Cigna Pharmacy & Therapeutics Committee member is included on either list:

- [OIG exclusions](#) &
- [Sam.gov](#)

ICOG staff subsequently reports results to both Chief Clinical Guidance Officer, ICOG and the Medicare Chief Compliance Officer.

In terms of factors given more weight, drugs with a designation of Include are recommended for placement on all formularies. A drug may be given an Include designation if it meets at least one of the clinical bases and is anticipated via claims data, to treat a relatively large patient population.

The clinical basis includes unique indication for use addressing a clinically significant unmet treatment need, efficacy superior to that of existing therapy alternatives, a safety profile superior to that of existing therapy alternatives, a unique place in therapy, and/or drugs which treat medical conditions that necessitate individualized therapy and for which there are multiple treatment options.

When deciding whether to place a drug on a three-tiered formulary, and, if so, on which formulary tier, the formulary committee considers the following factors: the brand or generic status of a drug; whether, as applicable, a brand drug has available generic alternatives; whether the drug is the lowest net cost drug as compared to therapeutic alternatives; and whether a rebate arrangement exists for the drug to offset its cost.

The source for the brand or generic status factor is a publication of drug indicators available from an external vendor (First DataBank). The sources for whether a drug has available generic alternatives are available drug indicators from First DataBank and other external information about other drugs available in the same therapeutic class. The sources for whether the drug is the lowest net cost drug as compared to therapeutic alternatives is internal drug claims utilization information. The source for whether a rebate arrangement exists for the drug to offset its cost is rebate contract or billing information.

Application:

Committee Composition

Cigna includes in step four below the details around the committees responsible for the process and strategies of formulary design. Cigna's PBM Express Scripts has many years of formulary

development expertise and an extensive clinical pharmacy department that we tap into. Cigna develops formularies through a four-step process involving the work of three distinct committees:

- Pharmacy & Therapeutics Committee
- Healthcare Value Assessment Committee (HVAC)

Pharmacy & Therapeutics Committee - 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.

Healthcare Value Assessment Committee: The Cigna HVAC is responsible for all Prescription Drug List changes related to drug access (including tier placement) and UM (including PA, ST, QL, and therapeutic interchange requirements) and ongoing evaluation of Cigna Healthcare's Prescription Drug Lists from a drug access and cost perspective. For example, the HVAC is responsible for decisions to:

- Change tier assignments of existing Prescription Drug List drugs
- Add or remove drugs from the Prescription Drug List(s)
- Add or remove UM programs (PA, ST, QL, or therapeutic interchange requirements) to drug products
- Review newly FDA-approved drugs placed on the 180-day Prescription Drug List placement hold table by the Industry Codeset Committee (see policy PH-THP-21 titled “New Drug Management Policy”)
- Add or remove from coverage a drug product due to the implementation of a plan benefit exclusion (e.g. exclusion for sexual dysfunction treatment) by the applicable commercial group or individual Product segment.

The HVAC is also responsible for instructing through briefs and meeting minutes the implementation of approved changes and also overseeing implementation of changes. For formularies maintained and developed by Cigna Healthcare, the authority to make negative Prescription Drug List changes rests solely with the HVAC, except for removals of a drug product from a Prescription Drug List due to its withdrawal from the market.

Non-clinical factors HVAC principally considers are the brand or generic status/availability of drugs and the financial value of drugs.

The process to submit information for a formulary exception is as follows:

1. Utilization Review/Management

The Coverage Review Operations Department reviews requests based on criteria developed consistent with the clinical parameters recommended by the P&T Committee. The P&T Committee is comprised of independent practicing clinicians representing a range of specialties, including MH/SUD treatment expertise, also reviews and approves all prior authorization requirements, as well as the medical necessity coverage criteria used to review any prior authorization requests for

the drugs subject to prior authorization. This ensures that decisions to apply prior authorization, and the criteria to review prior authorization requests, aligns with available clinical evidence like FDA-product labeling, clinical literature, and clinical guidelines.

2. Review processes

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. If member does not meet criteria or is ineligible under the plan, then an administrative denial is issued regardless of whether the drug is used to treat an MH/SUD or M/S condition.

With respect to clinical reviews of drugs for medical necessity, for either an MH/SUD or M/S drug an appropriate practitioner under NCQA guidelines must issue any denial, and any appeal of denied must be handled by a practitioner not involved in the initial decision. Consistent with applicable law and accreditation standards, all denials, whether for MH/SUD or M/S drugs, must include, among other data elements, a denial reason and any appeal rights afforded to the enrollee by applicable law.

3. Minimum qualifications for reviewers when issuing a denial

If denial determinations have been delegated to Cigna for review, the requests will be forward to a utilization management pharmacist. The utilization management pharmacist reviews denial and appeal request (whether MH/SUD or M/S drugs) pursuant to coverage policies approved by the clinical P&T Committee, which is comprised of practicing clinicians representing a range of specialties, including, by virtue of inclusion of a psychiatrist on the P&T Committee, MH/SUD treatment, to ensures that criteria and decisions aligns with available clinical evidence like FDA-product labeling, clinical literature, and clinical guidelines.

4. Timelines and deadlines

Cigna adheres to state and federal timeliness standards for both M/S and MH/SUD drug determinations including formulary exceptions.

As noted in step 2, if the P&T Committee finds that a drug must be covered on the formulary as a clinical matter, then the HVAC must place the drug on the formulary. If the P&T Committee determines that a drug may or may not be covered on the formulary as a clinical matter, then the HVAC may consider other factors, including economic factors, in deciding whether to place the drug on the formulary. Any of the factors may be considered, and the factor that is given more weight is Pharmacy and Therapeutics ("P&T") Committee clinical safety and efficacy evaluation and designation.

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:

The NQTL document represents a comparative analysis of the parameters applied to mental health/substance use disorder ("MH/SUD") and/or medical/surgical ("M/S") services and incorporated in plans insured by CHLIC.

The Mental Health Parity (MHP) Non-Quantitative Treatment Limitation (NQTL) comparative analysis is created through a multi-step process which includes:

- Ensuring appropriate documentation of Cigna's methodologies, factors, and evidentiary standards; and
- Writing a detailed summary explanation of how the analyses of all the specific underlying processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits and to medical/surgical benefits have led the plan to confirm compliance with MHPAEA.

Conducting the comparative analysis is not a onetime occurrence; it's an ongoing occurrence. Ongoing occurrence means weekly, monthly, quarterly meetings with business, legal, compliance, data and analytics, subject matter experts. The analysis is performed by members of the compliance team, various business subject matter experts, pharmacists, and senior medical directors. Each document is reviewed and finalized by the legal team. On an annual basis Cigna reviews the formulary data and reports. e.g., Formulary Summary and audit reports that are generated by formulary data. Cigna conducts a comparison of the MH/SUD and M/S data - on/off

formulary, generic, specialty drugs, tier placement. Once the data is reviewed, Cigna identifies discrepancies, common themes, and trends. Depending on results of the analysis, Cigna's review may warrant policy changes, changes in procedures, change processes, the types of relevant data collected and continue to monitor the results. The methodology is not just a collection of artifacts. As mentioned, the methodology is ongoing discussion with the business, legal, compliance, data and analytics, subject matter experts. Elements considered and reviewed in the comparative analysis: Reports, data, policies, procedures, audits, laws and new regulations. This is demonstrated in our analysis by the inclusion of reports, policies and procedures, formulary details.

As far as methodology used to decide whether to place a drug on a three-tiered formulary, and, if so, on which formulary tier, the formulary committee considers the following factors:

the brand or generic status of a drug; whether, as applicable, a brand drug has available generic alternatives; whether the drug is the lowest net cost drug as compared to therapeutic alternatives; and whether a rebate arrangement exists for the drug to offset its cost.

The specific explanation for the methodology to determine tier assignment/higher copayment for each tier and whether the methodology is the same for MH/SUD and M/S medications is as follows:

Once the Healthcare Value Assessment Committee decides to place a drug on the formulary, the drug's tier placement is determined. The parameters for tier placement of drugs differs by formulary and are summarized below. While these parameters describe how most drugs are placed on specific formulary tiers, other considerations, such as competitive landscape and legal/regulatory requirements, may also dictate the tier placement of specific drugs.

- Tier 1: Generic drugs
- Tier 2: Brand drugs may be designated to Tier 2 based on a combination of factors, which may include:
 - Drugs with high clinical value as determined by the P&T Committee; or
 - Lowest-net cost drug product within a class/condition.
- Tier 3: Brand drugs are generally assigned to Tier 3, unless placement on Tier 2 is warranted based on the parameters for Tier 2 placement described in this charter.
- Tier 4: For a four-tier formulary, specialty drugs, including specialty brand drugs and specialty generic drugs, are covered on Tier 4. Non-specialty drugs are covered in accordance with the tier definition for three-tier formularies set forth above.

The methodology used to determine tier assignment for medications in other outpatient settings and whether the methodology is the same for MH/SUD and M/S medications is as follows:

General methodology used to determine tier assignment for medications is the same methodology followed in the outpatient setting.

With regards to behavioral health/mental health conditions, Carrier offers to large group policyholders several three and four-tier formulary designs as part of the prescription drug benefit. When placing a pharmaceutical product on a formulary and, if covered on a formulary, a particular formulary tier, Carrier considers the following factors: whether the pharmaceutical product is covered by the policy (e.g. is the product used to treat a covered condition); the status of a pharmaceutical product as a brand, generic and/or specialty product; the clinical safety/efficacy of

the product as communicated by the P&T Committee; and economic information like pharmaceutical product cost. If covered on a formulary, Carrier places a product on a cost-sharing tier based on its status as a brand, generic, and/or specialty product, with many specialty products covered on one of the highest cost-sharing tiers and low-cost generic products covered on the lowest cost-sharing tiers. Tier 1 of the formulary covers generic products. Tier 2 of the formulary covers preferred brand products. Tier 3 covers non-preferred brand products. Tier 4, if elected by the policyholder, covers oral and/or injectable specialty products (whether generic or brand). Some drugs are not covered on any formulary tier; these drugs may be referred to, for example, as "non-formulary." Brand products are assigned to a cost-sharing tier (Tier 2 or Tier 3) that is higher than generic products, and, among those tiers, based on consideration of the product's cost (total net cost of product, inclusive of ingredient cost and available manufacturer revenue) and whether the P&T Committee permits a given product to be preferred over another, therapeutically similar product(s). If the large group policyholder elects to include a fourth specialty tier (Tier 4) as a part of the plan design, then oral and/or injectable specialty products – regardless of whether the specialty drug is used to treat a mental health/substance use disorder or medical/surgical condition – are placed on that specialty tier.

With regards to substance use disorders, Carrier offers to large group policyholders several three and four-tier formulary designs as part of the prescription drug benefit. When placing a pharmaceutical product on a formulary and, if covered on a formulary, a particular formulary tier, Carrier considers the following factors: whether the pharmaceutical product is covered by the policy (e.g. is the product used to treat a covered condition); the status of a pharmaceutical product as a brand, generic and/or specialty product; the clinical safety/efficacy of the product as communicated by the P&T Committee; and economic information like pharmaceutical product cost. If covered on a formulary, Carrier places a product on a cost-sharing tier based on its status as a brand, generic, and/or specialty product, with many specialty products covered on one of the highest cost-sharing tiers and low-cost generic products covered on the lowest cost-sharing tiers. Tier 1 of the formulary covers generic products. Tier 2 of the formulary covers preferred brand products. Tier 3 covers non-preferred brand products. Tier 4, if elected by the policyholder, covers oral and/or injectable specialty products (whether generic or brand). Some drugs are not covered on any formulary tier; these drugs may be referred to, for example, as "non-formulary." Brand products are assigned to a cost-sharing tier (Tier 2 or Tier 3) that is higher than generic products, and, among those tiers, based on consideration of the product's cost (total net cost of product, inclusive of ingredient cost and available manufacturer revenue) and whether the P&T Committee permits a given product to be preferred over another, therapeutically similar product(s). If the large group policyholder elects to include a fourth specialty tier (Tier 4) as a part of the plan design, then oral and/or injectable specialty products – regardless of whether the specialty drug is used to treat a mental health/substance use disorder or medical/surgical condition are placed on that specialty tier.

With regards to medical/surgical conditions, Carrier offers to large group policyholders several three and four-tier formulary designs as part of the prescription drug benefit. When placing a pharmaceutical product on a formulary and, if covered on a formulary, a particular formulary tier, Carrier considers the following factors: whether the pharmaceutical product is covered by the policy (e.g., is the product used to treat a covered condition); the status of a pharmaceutical product as a brand, generic and/or specialty product: the clinical safety/efficacy of the product as communicated by the P&T Committee; and economic information like pharmaceutical product cost. If covered on a formulary, Carrier places a product on a cost-sharing tier based on its status as

a brand, generic, and/or specialty product, with many specialty products covered on one of the highest cost-sharing tiers and low-cost generic products covered on the lowest cost-sharing tiers. Tier 1 of the formulary covers generic products. Tier 2 of the formulary covers preferred brand products. Tier 3 covers non-preferred brand products. Tier 4, if elected by the policyholder, covers oral and/or injectable specialty products (whether generic or brand). Some drugs are not covered on any formulary tier; these drugs may be referred to, for example, as "non-formulary." Brand products are assigned to a cost-sharing tier (Tier 2 or Tier 3) that is higher than generic products, and, among those tiers, based on consideration of the product's cost (total net cost of product, inclusive of ingredient cost and available manufacturer revenue) and whether the P&T Committee permits a given product to be preferred over another, therapeutically similar product(s). If the large group policyholder elects to include a fourth specialty tier (Tier 4) as a part of the plan design, then oral and/or injectable specialty products – regardless of whether the specialty drug is used to treat a mental health/substance use disorder or medical/surgical condition – are placed on that specialty tier.

The coverage of drugs covered on Cigna's formularies are, subject to a client policyholder's election, as applicable, determined by two internal/affiliated committees that perform different, but interrelated, functions: the Pharmacy & Therapeutics Committee ("P&T Committee"); and the Healthcare Value Assessment Committee (HVAC).

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.

The Committee evaluates a drug after its approval by the FDA. Pharmacists conduct a search of medical literature, review published data from clinical trials and the FDA approved package insert. Pharmacists also contact the pharmaceutical manufacturer to obtain and evaluate additional safety and efficacy that led to the product's FDA approval. The pharmacists may also contact physician specialists to obtain additional information and review medical practice guidelines relevant to the drugs approved indication. A thorough clinical review is conducted, included medication pharmacology, safety, efficacy, and dosage. The clinical information on the drug under review is then compared to clinical information on pharmacologic and non-pharmacologic therapy alternatives.

In terms of time allocated for deliberations, after review of the information, and discussion among P&T members, the Committee will vote if the drug should be given the status of Include, Access, Optional, or Exclude on the formulary. The committee must base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, outcomes research data, and incorporating their own clinical practice expertise. Financial information will be neither discussed nor impact the committee's clinical decisions.

Reasonable effort will be made to review drugs within 90 days of release onto the market in the U.S., and decisions will be made within 180 days of introduction to the marketplace. For medications meeting the CMS definition of Protected Class, the Committee will review and make formulary placement decisions within 90 days of a new product introduction or newly approved use for an existing product.

The P&T Committee currently consists of actively practicing physicians and pharmacists. The Committee includes a board-certified psychiatrist who treats a wide range of psychiatric conditions. It also includes multiple physicians (geriatrician, pediatrician, internal medicine, etc.) who also commonly address mental health and substance use issues. Members are selected by the Committee based on contributions to medical and pharmacy literature, national recognition in their specialty, involvement in clinical (patient care) practice (membership prerequisite), and previous experience with P&T committees.

First, as for the comparability of experts for MH/SUD conditions and M/S conditions, the following medical and pharmacy specialties are represented on Cigna's P&T Committee: Cardiology, Dermatology, Endocrinology, Gastroenterology, Geriatrics, Internal Medicine, Neurology, Obstetrics & Gynecology, Oncology, Pediatrics, Pharmacy (Geriatrics), Psychiatry, Pulmonology, and Rheumatology. While it may appear that there is only one specializing in MH, Psychiatry, as mentioned above, there are multiple physicians that commonly address MH/SUD issues. All experts are held to nationally recognized standards in their practice area(s). The Committee has frequently consulted with outside, independent experts for a variety of substance use disorder medications and therapy classes. Outside expertise is formally presented to the Committee for decision-making purposes. For medical/surgical, these are all actively practicing physicians and pharmacists with a wide range of day-to-day interactions. At least one of our physicians (OB/GYN) is actively involved in a variety of surgical interventions. The panel of experts on the P & T committee is deemed to meet the NQTL stringency and comparability requirements because each expert consistently applies their knowledge to MH/SUD and M/S drug formulary recommendations.

Second, as for the comparability of evaluation and application of nationally recognized treatment guidelines used by the experts, each treatment guidelines, MH/SUD and M/S, are applied comparably and no more stringently because each expert utilizes nationally recognized treatment guidelines as appropriate in their position on the P & T Committee. Additionally, there is an annual internal review to determine the P & T Committee's panel of experts determinations of whether a treatment is medically appropriate and comprised of comparable experts for MH/SUD conditions and M/S conditions. As part of the annual review, such experts evaluate and apply nationally recognized treatment guidelines in a comparable manner MH/SUD versus M/S.

Pharmacy & Therapeutics Committee (Annual Review) —On an annual basis, the P&T Committee will review the final formulary recommendations, by drug class, for the upcoming plan year. The Committee uses this opportunity to ensure adherence to previously established formulary placement recommendations, and to validate continued alignment with best medical practices. The Committee also ensures that all Cigna's national formularies cover a broad distribution of therapeutic classes and categories, and that the formularies neither discourage enrollment by any group of enrollees nor discriminate against certain patient populations.

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 or PBM/health plan operations, 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

If the P&T Committee finds that a drug must be covered on the formulary as a clinical matter, then the Healthcare Value Assessment Committee must place the drug on the formulary. If the P&T Committee determines that a drug may or may not be covered on the formulary as a clinical matter, then the Healthcare Value Assessment Committee may consider other factors, including economic considerations, when deciding whether to place the drug on the formulary. To clarify all committee members are collectively responsible for making decisions about whether about a drug should be covered on the formulary regardless of whether the drug is M/S or MH/SUD. Moreover, the participation in the P&T Committee of a practicing psychiatrist ensures comparable representation of MH/SUD expertise when drugs are assessed for clinical safety/efficacy in the context of formulary placement and tiering.

The process for reviewing drugs for coverage does not differ by whether the drug is used to treat an M/S condition or a MH/SUD condition.

In terms of timing allocation of decisions, the HVAC meets and reviews information, including relevant clinical, economic, and business considerations, and make decisions on a regular basis, at least monthly. All new products and proposals will be reviewed at that time. In terms of the timing of decisions around alignment of the P&T Committee and Healthcare Value Assessment Committee

typically review all new-to-market drugs, whether MH/SUD or M/S drugs, within six months of market availability, and typically reviews potential opportunities to make formulary changes outside the context of new-to-market drug entries up to twice per year.

As described in detail under the narrative response to Steps 2, Cigna considers the same factors and accompanying evidentiary standards when designing its large group and individual formularies. The same P&T and Healthcare Value Assessment Committee structure reviews M/S and MH/SUD drugs for formulary placement and whether to subject a drug to a prior authorization requirement, and pursuant to common policies and procedures.

In terms of decision-making authority making for MH/SUD drugs outlined is an explanation of HVAC Committee compared to the P&T Committee. HVAC establishes formulary and tier placement as well as UM strategies for the reviewed drug, after the P&T Committee review. Then the proposed HVAC decision goes back to the P&T Committee for review under the P&T Committee's scope of responsibilities within the six-month timeframe. The HVAC remediates any deficiencies identified by the P&T Committee in its holistic clinical review of the formularies based on the proposed HVAC decision. Under the P&T Standards of Evidence Review, which occurs after the P&T Committee has completed its clinical evidence-based determination on the relative safety and efficacy of a drug, the drug may be considered for review by the HVAC. The P&T Committee's clinical findings on the drug will govern HVAC decision when considering the medication for formulary placement of other UM decisions.

The P&T Committee determines which medications must clinically be available on a formulary. "Include" medications must be available. "Exclude" medications may not be placed on the preferred brand tier. "Access" medications must be available either on the formulary or via formulary exception criteria. "Optional" medications may or may not be available. HVAC reviews these parameters and, according to the descriptions above, establishes the necessary tier placement.

The HVAC has ultimate accountability for ensuring all decisions related to the creation and maintenance of Prescription Drug Lists adhere to the P&T Committee's clinical findings, legal/regulatory requirements, and accreditation standards (see HVAC Charter). The HVAC and its chartered subcommittee, the Industry Codeset Committee, determine and oversee implementation of Prescription Drug List changes according to the scope of responsibilities, as outlined in the committees' respective charters and set forth in this section.

Healthcare Value Assessment Committee:

The HVAC is responsible for all Prescription Drug List changes related to drug access (including tier placement) and UM (including PA, ST, QL, and therapeutic interchange requirements) and ongoing evaluation of Cigna Healthcare's Prescription Drug Lists from a drug access and cost perspective. For example, the HVAC is responsible for decisions to:

- Change tier assignments of existing Prescription Drug List drugs
- Add or remove drugs from the Prescription Drug List(s)
- Add or remove UM programs (PA, ST, QL, or therapeutic interchange requirements) to drug products

- Review newly FDA-approved drugs placed on the 180-day Prescription Drug List placement hold table by the Industry Codeset Committee (see policy PH-THP-21 titled “New Drug Management Policy”)
- Add, or remove from, coverage a drug product due to the implementation of a plan benefit exclusion (e.g. exclusion for sexual dysfunction treatment) by the applicable commercial group or individual Product segment.

The HVAC is also responsible for instructing through briefs and meeting minutes the implementation of approved changes and also overseeing implementation of changes. For formularies maintained and developed by Cigna Healthcare, the authority to make negative Prescription Drug List changes rests solely with the HVAC, except for removals of a drug product from a Prescription Drug List due to its withdrawal from the market.

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 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 ad 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.

- Tier 1: Generic drugs
- Tier 2: Brand drugs may be designated to Tier 2 based on a combination of factors, which may include:
 - Drugs with high clinical value as determined by the P&T Committee; or
 - Lowest-net cost drug product within a class/condition.
- Tier 3: Brand drugs are generally assigned to Tier 3, unless placement on Tier 2 is warranted based on the parameters for Tier 2 placement described in this charter.
- Tier 4: For a four-tier formulary, specialty drugs, including specialty brand drugs and specialty generic drugs, are covered on Tier 4 (as applicable to plan) . Non-specialty drugs are covered in accordance with the tier definition for three-tier formularies set forth above.

The total number of MH/SUD and M/S drugs on the Standard 3 tier formulary that are generic are 93.88% of MH/SUD Tier 1 and M/S drugs on formulary that are generic is 88.23%, respectively. 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. 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 there are more generics for MH/SUD.

2026				
Standard 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,645	
On Formulary	11,204	95.84%	52,340	90.80%
Off Formulary	486	4.16%	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%

In terms of operational parity compliance, Cigna has also assessed as follows across its group formularies. First, a comparable percentage of MH/SUD drug NDCs are covered on v. off-formulary as compared to M/S drug NDCs under such formularies (about 4.47% of MH/SUD and 5.68% 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.

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 v. off-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.

In terms of branded MH/SUD drugs that have been excluded from the formulary, there are no true excluded drugs for MH/SUD that have been excluded from the formulary. There are no drugs that are considered a true exclusion. Drugs not covered still have a path to access. Even if a drug is non-

formulary, there is a path for medical necessity via providers. A true Exclude is, for example, over the counter drugs and compound drugs, which are not commercially available and have to be compounded by a pharmacy.

Set forth below in the Specialty Drug List Summary of On Formulary and Off Formulary table provides evidence in-operation comparability for MH/SUD and M/S medications showing the amount of how many drugs have PA, Step Therapy, QL, and excluded. For the numerical results below the numerators are the total of specialty drugs of M/S or MH/SUD, the denominators are total amount of drugs of M/S or MH/SUD, the source of the data is the Commercial 3 Tier.

M/S vs MH/SUD Specialty Drugs

Advantage 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	12,030		66,548	
Total Specialty Drugs	35	0.29%	6538	9.82%
Total Specialty PA	19	0.16%	3982	5.98%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1495	2.25%
Specialty Exclude of All	4	0.03%	726	1.09%
Specialty On Formulary				
Total Specialty Drugs	31	0.26%	5812	8.73%
Total Specialty PA	19	0.16%	3937	5.92%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	17	0.14%	1221	1.83%
Specialty Exclude of Specialty	0	0.00%	0	0.00%
Specialty Non-Formulary				
Total Specialty Drugs	4	0.03%	726	1.09%
Total Specialty PA	0	0.00%	45	0.07%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	2	0.02%	274	0.41%
Specialty Exclude of Specialty	4	11.43%	726	11.10%
Legacy 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,645	
Total Specialty Drugs	23	0.20%	4605	7.99%
Total Specialty PA	23	0.20%	3130	5.43%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1492	2.59%
Specialty Exclude of All	0	0.00%	481	0.83%
Specialty On Formulary				
Total Specialty Drugs	23	0.20%	4124	7.15%
Total Specialty PA	23	0.20%	2678	4.65%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1471	2.55%
Specialty Exclude of Specialty	0	0.00%	0	0.00%
Specialty Non-Formulary				
Total Specialty Drugs	0	0.00%	481	0.83%

Total Specialty PA	0	0.00%	452	0.78%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	0	0.00%	21	0.04%
Specialty Exclude of Specialty	0	0.00%	481	10.45%
Legacy Performance 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	12,030		66,946	
Total Specialty Drugs	35	0.29%	6540	9.77%
Total Specialty PA	23	0.19%	4637	6.93%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1495	2.23%
Specialty Exclude of All	0	0.00%	74	0.11%
Specialty On Formulary				
Total Specialty Drugs	35	0.29%	6466	9.66%
Total Specialty PA	23	0.19%	4592	6.86%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1479	2.21%
Specialty Exclude of Specialty	0	0.00%	0	0.00%
Specialty Non-Formulary				
Total Specialty Drugs	0	0.00%	74	0.11%
Total Specialty PA	0	0.00%	45	0.07%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	0	0.00%	16	0.02%
Specialty Exclude of Specialty	0	0.00%	74	1.13%
Performance 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	12,030		66,946	
Total Specialty Drugs	35	0.29%	6540	9.77%
Total Specialty PA	19	0.16%	3970	5.93%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1495	2.23%
Specialty Exclude of All	4	0.03%	736	1.10%
Specialty On Formulary				
Total Specialty Drugs	31	0.26%	5804	8.67%
Total Specialty PA	19	0.16%	3929	5.87%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	17	0.14%	1221	1.82%
Specialty Exclude of Specialty	4	12.90%	0	0.00%
Specialty Non-Formulary				
Total Specialty Drugs	4	0.03%	736	1.10%
Total Specialty PA	0	0.00%	41	0.06%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	2	0.02%	274	0.41%
Specialty Exclude of Specialty	4	11.43%	736	11.25%

Standard 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,645	
Total Specialty Drugs	23	0.20%	4605	7.99%
Total Specialty PA	19	0.16%	2527	4.38%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1492	2.59%
Specialty Exclude of All	4	0.03%	1071	1.86%
Specialty On Formulary				
Total Specialty Drugs	23	0.20%	3534	6.13%
Total Specialty PA	19	0.16%	2080	3.61%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	17	0.15%	1222	2.12%
Specialty Exclude of Specialty		0.00%	0	0.00%
Specialty Non-Formulary				
Total Specialty Drugs	4	0.03%	1071	1.86%
Total Specialty PA	0	0.00%	447	0.78%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	2	0.02%	270	0.47%
Specialty Exclude of Specialty	2	8.70%	1071	23.26%
Value 3-Tier	MH/SUD	MH/SUD %	M/S	M/S %
Total Covered Drugs	11,690		57,350	
Total Specialty Drugs	23	0.20%	4605	8.03%
Total Specialty PA	19	0.16%	2541	4.43%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	19	0.16%	1492	2.60%
Specialty Exclude of All	4	0.03%	1057	1.84%
Specialty On Formulary				
Total Specialty Drugs	19	0.16%	3548	6.19%
Total Specialty PA	19	0.16%	2094	3.65%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	17	0.15%	1217	2.12%
Specialty Exclude of Specialty	4	21.05%	0	0.00%
Specialty Non-Formulary				
Total Specialty Drugs	4	0.03%	1057	1.84%
Total Specialty PA	0	0.00%	447	0.78%
Total Specialty ST	0	0.00%	0	0.00%
Total Specialty QL	2	0.02%	275	0.48%
Specialty Exclude of Specialty	4	17.39%	1057	22.95%

Number of medications: As you can see from the data, there are more M/S specialty drugs than specialty MH/SUD drugs. The reason why there are more M/S specialty drugs than MH/SUD is due to the complexity of disease states, for example, oncology and blood disorders whereas MH/SUD drugs have a narrower scope and do not require extensive treatments within the specialty realm. As a reminder, what makes a specialty drug is the special handling, complexity of the disease, requires more patient interaction and may require administration by a healthcare professional. In

short, specialty drugs must be handled in a specific way, but for MH/SUD drugs and the nature of the drugs are not such that they have to be handled in that way. Hence, why there are more specialty drugs in M/S as compared to MH/SUD.

Prior Authorizations:

On these Cigna formulary plans, approximately 7% or less of specialty M/S drugs require a specialty prior authorization whereas less than 0.2% of MH/SUD drugs require a specialty prior authorization. As seen by this data, Cigna Healthcare is less restrictive with specialty MH/SUD drugs than with specialty M/S drugs.

Step Therapy:

No Cigna formulary plans include or require step therapy on specialty M/S or specialty MH/SUD drugs.

Quantity Limits:

When comparing quantity limits for specialty MH/SUD drugs vs. specialty M/S drugs, Cigna Healthcare places a quantity limit (QL) for less than 0.2% of covered drugs in the MH/SUD category. For specialty M/S drugs, Cigna Healthcare places a QL for less than 2.6% of covered drugs. This difference in percentages between MH/SUD and M/S in this category can be explained by the fact that a large portion of specialty drugs are M/S medications rather than MH/SUD, please refer to the narrative within the “number of medications” which explains the reasoning as to why there are a larger portion of specialty drugs in M/S. As seen by this data, Cigna Healthcare is less restrictive with specialty MH/SUD medications than with specialty M/S medications.

Excluded Medications:

When comparing specialty medication exclusions for MH/SUD drugs vs. specialty medication exclusions for M/S drugs, Cigna Healthcare excludes <1% of covered drugs in the MH/SUD category. For M/S specialty drugs, Cigna Healthcare excludes less than 2% of covered drugs. As seen by this data, Cigna Healthcare is less restrictive with specialty MH/SUD drugs than with specialty M/S medications.

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%

Prior Authorizations:

On these Cigna formulary plans, approximately 17% or fewer M/S drugs require a prior authorization; comparably approximately 14% or fewer MH/SUD drugs require a prior authorization. As seen by this data, Cigna Healthcare requires prior authorization comparably across M/S and MH/SUD non-specialty medications.

Step Therapy:

M/S requires step therapy on <1% of medications across all formularies and MH/SUD requires step therapy on <1.5 % of medications.

Quantity Limits:

When comparing quantity limits for MH/SUD drugs vs. M/S drugs, Cigna Healthcare places a quantity limit (QL) on a higher percentage of MH/SUD drugs. This difference in percentages

between MH/SUD and M/S in this category can be explained by the fact that a higher relative proportion of MH/SUD drugs as compared to M/S drugs present safety concerns, including and especially being recognized as controlled substances under federal law.

Excluded Medications:

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

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

Pharmacy Summary Methodology - MEDSURG and MHSUD On and OFF Formulary Analysis

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	Z=Drug is part of a Buy-up category

Tiers 1 and 2 – N, X, Y, and Z are exclusions for M/S, these exclusions were used to determine on vs. off formulary for M/S Tier 3 – N are new drugs normally placed on Tier 3 were included in the on-formulary calculations for M/S.

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
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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
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Standard:

- 8-10% savings compared to a less managed formulary

- Broader formulary balances choice and affordability, with a wide range of brand-name and generic drugs and a limited list of non-formulary brand drugs
- Affordability through overall lower front-end claim costs
- Generally, offer multiple therapeutically equivalent drugs within copay tiers

Performance:

- 8-10% savings compared to a less managed formulary
- Broader formulary balances choice and affordability, with a wide range of brand-name and generic drugs and a limited list of non-formulary brand drugs
- Affordability through overall lower front-end claim costs
- Generally, offer multiple therapeutically equivalent drugs within copay tiers

Value:

- 4-6% savings compared to Standard and Performance formularies
- Drives greatest affordability by removing more brand drugs and offering fewer preferred brands compared to other formularies, offering exclusivity in select classes/conditions
- Affordability through lower front-end claim costs due to generic drug focus and drug removals and exclusions: Proton Pump Inhibitors (PPIs) and non-sedating antihistamines (NSAs) are not covered – they are available over the counter and can be added back in/generics only
- Focused on net cost savings

Advantage:

- 4-6% savings compared to Standard and Performance formularies
- Drives greatest affordability by removing more brand drugs and offering fewer preferred brands compared to other formularies, offering exclusivity in select classes/conditions
- Affordability through lower front-end claim costs due to generic drug focus and drug removals and exclusions: Proton Pump Inhibitors (PPIs) and non-sedating antihistamines (NSAs) are not covered – they are available over the counter and can be added back in/generics only focused on net cost savings

Applicable to all formularies:

- Actively managed
- 3- and 4-tier options - the 4-tier version moves all Specialty drugs to fourth tier
- Semi-annual changes to protect against egregious pricing and to take advantage of therapeutically equivalent drugs and generics
- Non-formulary drugs covered only when determined medically necessary
- Utilization management edits (quantity limits, step therapy, prior authorization) to support formulary control and safe, effective and affordable drug options

Audits Performed

Audits performed to validate the NQTLs applied to drugs are in fact implemented in the way they are defined in writing and that Step Therapy, Prior Authorization, Quantity Limits were applied as defined for MH/SUD are set forth below:

Annual step therapy, prior authorization, and quantity limits audit - Cigna reviews the top 10 M/S and MH/SUD drugs that have ST, PA, QL reviews, and reviews the requirements of the drugs that are part of the approvals and denials. This ensures processes are applied as-written and mandates are being followed properly.

Based on the review, the cases that were denied were denied appropriately with no alternatives/or additional information provided by physicians. Some were overturned once additional information was received. It was clarified with the Cigna pharmacists that some were denied because the patient only tried “samples” of the medications, and according to the pharmacy’s Anti-couponing/sampling policy, samples as established therapy.

General Requirements.

A carrier may not impose a step therapy or fail-first protocol on a customer if:

- The step-therapy drug has not been approved by the U.S. FDA for the medical condition being treated; or
- A prescriber provides supporting medical information to the carrier that a prescription drug covered by the carrier:
 - was ordered by a prescriber for the customer within the past 180 days; and
 - based on the professional judgment of the prescriber, was effective in treating the customer's disease or medical condition.

This law does not require coverage for a prescription drug that is not:

- Covered by the policy or contract; or
- Otherwise required by the law to be covered.

Monthly Pharmacy Appeals Turnaround Time Audit

Ensures the correct turn-around-times (TAT) being applied to Commercial pharmacy claims according to the level of the appeal and the state requirements.

Quarterly Prescription Drug List View Audit

To establish compliance review of newly installed (or amended) Cigna Commercial Standard Prescription Drug Formularies to ensure the accuracy of Cigna's Commercial Prescription Drug Formularies. This audit ensures that when changes and/or updates are made to the Cigna Commercial Standard Prescription Drug Formularies the online tool available for viewing those formularies (by patients, customers, providers, or other interested stakeholders) is displaying accurately for those who may receive benefits through Cigna, and/or who are attempting to procure services and understand their benefit options.

Cigna Pharmacy Online Directory Audit (PDL):

Audit of newly installed (or amended) Cigna Commercial Standard Prescription Drug Formularies to ensure accuracy of the Commercial Prescription Drug Formularies offered by Cigna. This audit will ensure that when changes and/or updates are made to the Cigna Commercial Standard Prescription Drug Formularies that the online tool available for viewing those formularies (by patients, customers, providers, or other interested stakeholders) is displaying accurately for those who may receive benefits through Cigna, and/or who are attempting to procure services and understand their benefit options. Data utilized is Cigna's Commercial Book of Business.

Commercial Book of Business

Quarter	Result	Pass/Fail 90% or greater to pass
1Q 2024	Top 100: 100% accuracy Random Sample: 98% accuracy	Pass

	1.1 Changes: 100% accuracy	
2Q 2024	Top 100: 99% accuracy Random Sample: 100% accuracy	Pass
3Q 2024	7.1 Changes: 100% accuracy	Pass
4Q 2024	Top 100: 98% accuracy Random Sample: 99% accuracy	Pass
1Q 2025	Top 100: 100% accuracy Random Sample: 98% accuracy 1.1 Changes: 100% accuracy	Pass
2Q 2025	Top 100: 99% accuracy Random Sample: 100% accuracy	Pass
3Q 2025	7.1 Changes: 100% accuracy	Pass
4Q 2025	Top 100: 98% accuracy Random Sample: 99% accuracy	Pass

The audit process takes into consideration changes to the formularies, as such, additional audits are performed whenever a change is made.

Cigna Pharmacy UM TAT- Audit to ensure UM Turnaround times are being met for Cigna PBM.

Cigna Pharmacy UM Turnaround Time	
Audit of Pharmacy utilization management reviews turnaround time utilizing Cigna's Commercial Book of Business Data. Accuracy percentage based on NCQA standards.	
Quarter	Result
3Q2024	99.2% accuracy
4Q2024	99.5% accuracy
1Q2025	99.7% accuracy
2Q2025	99.7% accuracy
3Q2025	99.7% accuracy
4Q2025	99.7% accuracy

If audit results fall below 90%, a Quality Improvement Plan is implemented.

Any Utilization Management assigned to a MH/SUD product is conducted at parity with other products in that class. The audit is performed at HVAC.

The measures that Cigna employs to ensure the comparability design and application of the multi-tiered formulary NQTL to MH/SUD and M/S prescription drug benefits are to ensure that the written policies governing how MH/SUD or M/S drugs are placed on the formulary and tiered, are uniform (i.e., on/off-formulary and tiering factors/standards) to ensure that the in-writing process and factors/standards relied on are comparable irrespective of the underlying use of the drug. Moreover, Cigna assesses outcomes data, including 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 of the formulary decision-making process. Finally, the P&T Committee annually reviews the formularies to ensure that the HVAC adheres to its clinical designations, irrespective of whether they are MH/SUD or M/S drugs, when making formulary placement/tiering decisions for Cigna's formularies.

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

entity.

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:

Moreover, as further evidence of comparability and equivalent stringency in-operation, Cigna has also assessed as follows across its formularies: a comparable percentage of MH/SUD drugs are

covered on v. off-formulary as compared to M/S drugs; a lower absolute number of MH/SUD drugs are covered off-formulary as compared to M/S drugs; a comparable, and indeed lower, percentage of MH/SUD brand drugs are covered on the non-preferred brand tier (Tier 3) relative to the total number of MH/SUD drugs covered on Tiers 1 and 2 of the formulary, as compared to the proportion of M/S drugs covered on Tier 3 relative to the total M/S drugs covered on Tiers 1 and 2 of the formulary. As all generic drugs covered on the formulary are placed on Tier 1 and no brand drugs are placed on Tier 1, whether MH/SUD or M/S benefits, the placement of drugs on Tier 1 of the formulary is deemed to meet the NQTL stringency and comparability requirements for formulary placement. Put differently, there are no differences in placement of covered generic drugs for MH/SUD or M/S drugs, as the evidentiary standard – which was consistently applied to the placement of MH/SUD and M/S drugs on the formulary – for Tier 1 placement is the generic status of a drug.

While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement. In this case, there were comparable and, in some cases more advantageous, outcomes for the placement and tiering of MH/SUD drugs as compared to M/S drugs based on the absolute number of, and incidence of, non-formulary v. formulary and, for on-formulary drugs, Tier 2 v. Tier 3 drugs. These comparable outcomes, along with the confirmation that the evidentiary standards and factors were actually applied consistently to MH/SUD drugs as compared to M/S drugs, evidence in-operation compliance in terms of comparability and equivalent stringency and by including a psychiatrist on the clinical P&T committee, Cigna ensures that comparable clinical expertise in treating MH/SUD conditions and M/S conditions is represented in the formulary decision-making process. While physicians, regardless of specialty, are qualified under their scope of licensure to review the clinical safety/efficacy profile of an MH/SUD drug just as readily as M/S drugs used to treat conditions that the physician may not specialize in treating, Cigna acknowledges the benefits to its formulary management process of including MH/SUD expertise on the clinical P&T Committee. In the context of NQTL compliance, the inclusion of a physician with appropriate MH/SUD treatment expertise on the clinical P&T Committee that assigns clinical designations to M/S and MH/SUD drugs evidences the comparability of the process by which formulary management decisions are made, in writing and in operation, across M/S and MH/SUD prescription drug benefits. Relatedly, it also helps to ensure for MH/SUD drugs the appropriate consideration of the factors and standards that inform Cigna's formulary management decisions. Moreover, Cigna does not distinguish, in writing, between M/S and MH/SUD benefits in its prescription drug formulary design for its large group plan formularies, and it takes steps to monitor the consistency of decision-making across MH/SUD and M/S drugs by performing policy reviews and assessing operational outcomes periodically. As described in detail under the narrative response to Step 2, Cigna considers the same factors and accompanying evidentiary standards for MH/SUD and M/S drugs when designing its large group formularies pursuant to a uniform formulary decision-making process. The written process for reviewing drugs for coverage does not differ by whether the drug is used to treat an M/S condition or a MH/SUD condition, and in terms of the timing of decisions, the P&T Committee and Healthcare Value Assessment Committee typically review all new-to-market drugs, whether MH/SUD or M/S drugs, within six months of market availability, and typically reviews potential opportunities to make formulary changes of any kind outside the context of new-to-market drug entries up to twice per year.

In summary, the comparative analysis reflected in this document demonstrates that the application of the multi-tiered formulary design NQTL is based on the factors articulated above for both M/S and MH/SUD, thus demonstrating compliance in-writing and in-operation. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement. In this case, there were comparable, and in some cases more advantageous, outcomes for the placement and tiering of MH/SUD drugs as compared to M/S drugs based on the absolute number of, and incidence of, non-formulary v. formulary and, for on-formulary drugs, Tier 2 v. Tier 3 drugs under large group formularies. These comparable outcomes, along with the confirmation that the evidentiary standards and factors were actually applied consistently to MH/SUD drugs as compared to M/S drugs in terms of the adherence to P&T Committee clinical designations, evidence in-operation compliance in terms of comparability and equivalent stringency. Consequently, Cigna concludes that the NQTL of formulary management was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

This version of the analysis was drafted and performed in 2026 based upon Cigna's 2026 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