

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.

Medical Necessity

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

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

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

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

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

Issuer Response:

This document represents an NQTL comparative analysis for Medical Necessity applied to mental health/substance use disorder ("MH/SUD") and/or medical/surgical ("M/S") services for the inpatient and outpatient benefit classifications and is incorporated in plans insured by Cigna Health and Life Insurance Company ("CHLIC")

Medical Necessity is collectively understood to be the standards used to determine whether a service or procedure is required to treat a specific condition, injury or disease. Cigna defines Medical Necessity as follows: medical, surgical, diagnostic, psychiatric, substance abuse or other health care technologies, supplies, treatments, procedures, or devices to be medically necessary if the following criteria are met:

- Required to diagnose or treat an illness, injury, disease or its symptoms;
- In accordance with generally accepted standards of medical practice;
- Clinically appropriate in terms of type, frequency, extent, site and duration;
- Not primarily for the convenience of the patient, physician or other health professional.
- Not more costly than an alternative service(s), medication(s) or supply(ies) that is at least as likely to produce equivalent therapeutic or diagnostic results with the same safety profile as to the prevention, evaluation, diagnosis or treatment of the member's sickness, injury, condition, disease or its symptoms; and
- Rendered in the least intensive setting that is appropriate for the delivery of the services, supplies or medications. Where applicable, the Medical Director or Review Organization may compare the cost-effectiveness of alternative services, supplies, medications, or settings when determining least intensive setting.

In the review and analysis of the Medical Necessity NQTL, Cigna reviewed policies applicable to Cigna and Evernorth Behavioral Health (EBH), Delegated Vendor(s), and M.C. Dean, Inc. plan certificate.

Evernorth Behavioral Health ("Evernorth," "EBH" or "Behavioral Health") an affiliate of CHLIC performs utilization reviews for MH/SUD benefits. Cigna Health Management, Inc., also an affiliate of CHLIC performs utilization reviews for M/S benefits not otherwise delegated to a separate entity. All entities collectively referred to as "Cigna" and references to "Cigna" contained herein include Evernorth Behavioral Health.

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. Cigna maintains corporate-wide policies applicable to multiple business segments including Cigna Healthcare (M/S) and Behavioral Health (MH/SUD), and policies applicable to specific business segments only.

Cigna’s medical necessity definition is based on the guidance/direction from the Department of Health and Human Services and the court’s direction on the meaning of medical necessity. **“Medically Necessary” or “Medical Necessity”** shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease; and (c) not primarily for the convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.(Kaminiski, 2007) National Academies of Sciences, Engineering, and Medicine. 2012. Perspectives on Essential Health Benefits: Workshop Report. Washington, DC: The National Academies Press. As such, M.C. Dean, Inc. plan reflects this language.

M.C. Dean, Inc. Plan Language
Covered Expenses The term Covered Expenses means expenses incurred by a person while covered under this plan for the charges listed below for: • services or supplies that are Medically Necessary for the care and treatment of an Injury or a Sickness, as determined by Cigna.¹ General Limitations No payment will be made for expenses incurred for you or any one of your Dependents: • expenses for supplies, care, treatment, or surgery that are not Medically Necessary.² Medically Necessary/Medical Necessity Health Care Services, supplies and medications provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, condition, disease or its symptoms, that are all of the following as determined by a Medical Director or Review Organization: • required to diagnose or treat an illness, Injury, disease or its symptoms; • in accordance with generally accepted standards of medical practice; • clinically appropriate in terms of type, frequency, extent, site and duration; • not primarily for the convenience of the patient, Physician or Other Health Professional; • not more costly than an alternative service(s), medication(s) or supply(ies) that is at least as likely to produce equivalent therapeutic or diagnostic results with the same safety profile as to the prevention, evaluation, diagnosis or treatment of your Sickness, Injury, condition, disease or its symptoms; and • rendered in the least intensive setting that is appropriate for the delivery of the services, supplies or medications. Where applicable, the Medical Director or Review Organization may compare the cost-effectiveness of alternative services, supplies, medications or settings when determining least intensive setting. In determining whether Health Care Services, supplies, or medications are Medically Necessary, the Medical Director or Review Organization may rely on the clinical coverage policies maintained by Cigna or the Review Organization. Clinical coverage policies may incorporate, without limitation and as applicable, criteria relating to U.S. Food and Drug Administration-approved labeling, the standard medical reference compendia and peer-reviewed, evidence-based scientific literature or guidelines.³

Glossary:

¹ M.C. Dean, Inc. Plan Booklet pg. 32 of 90

² M.C. Dean, Inc. Plan Booklet pgs. 55-56 of 90

³ M.C. Dean, Inc. Plan Booklet pgs. 81-82 of 90

1. The ASAM Criteria®: Objective guidelines developed and published by American Society of Addiction Medicine that help clinicians standardize treatment planning and determine where patients are placed in treatment, and how to provide continuing, integrated care and ongoing service planning. See [About the ASAM Criteria](#).
2. Concurrent Review: A request for service that occurs after an admission or treatment has begun even if it is the initial request.
3. Customer: anyone covered by a plan, including the person who signed up for the plan and any dependents. Customer may also be referred to as: member, patient, or enrollee.
4. Emergency/Emergent Care: Cigna defines an Emergency as a Medical or Behavioral health condition manifesting itself by acute symptoms of sufficient severity such that a prudent person could reasonably expect the absence of immediate medical or BH assessment or/and stabilization to result in:
 - Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child
 - Serious impairment to bodily functions
 - Serious dysfunction of any bodily organ or part
 - Imminent harm to self or others
5. Internally Developed Clinical Coverage Policies: These tools are evidence-based decision support tools which are intended to provide an objective review of available published literature and/or other published information regarding a particular clinical indication or topic. Coverage Policies are not product or plan language specific.
6. MCG™ Guidelines: unbiased, evidence-based clinical decision support to identify safe and effective treatments and guide the appropriate level of care. See [MCG Care Guidelines](#)
7. Mental Health/Substance Use Disorder (MH/SUD): Means benefits with respect to items or services for mental health conditions or substance use disorders that are included in the current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM), as defined under the term of the plan and in accordance with applicable federal and state law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the International Classification of Diseases (ICD), or state guidelines).
8. Medical/Surgical (M/S): Cigna defines M/S benefit as items or services for medical conditions or surgical procedures, as defined under the terms of the plan and in accordance with applicable federal and state law but does not include mental health or substance use disorder benefits. Any condition defined by the plan being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases ICD or state guidelines).
9. Peer Reviewer (for behavioral health): an independently licensed behavioral health practitioner from appropriate specialty areas. Peer-reviewers may be a doctorate level psychologists, addictionologists, or board-certified psychiatrists depending on the credentials of the practitioner requesting the service. Peer-reviewers may review with clinical peers regardless of sub-specialty (Child & Adolescent). Behavioral Health's psychologists shall not make denial determinations regarding reimbursement for inpatient care or reimbursement for prescription drugs.
10. Peer Reviewer (for medical): an independently licensed medical director.
A medical director must:

- Hold an active unrestricted license or certification to practice medicine in a state or territory of the United States
 - Unless expressly allowed by state or federal regulations, are located in a state or territory of the United States when conducting a peer clinical review
 - Are qualified as determined by the Senior Medical Director to render a clinical opinion about the medical condition, procedure and treatment under review
 - Hold a current and valid license in the same category as the ordering provider or as a Doctor of Medicine, or as a Doctor of Osteopathic Medicine.
11. Prior Authorization: The requirement that a provider (physician, hospital, etc.) obtain approval from Cigna *before* performing a particular procedure. Prior authorization may also be referred to as precertification, predetermination, and pre-approval.
 12. Provider/Practitioner: A licensed physician, non-physician health care practitioner, hospital or other facility, supplier, or other individual or entity involved in the delivery of health care services or benefits.

Supporting Documents:

Document/Policy Name	Description
MCG™ Guidelines	Unbiased, evidence-based clinical decision support to identify safe and effective treatments and guide the appropriate level of care.
The ASAM Criteria®	Objective guidelines developed and published by American Society of Addiction Medicine that help clinicians standardize treatment planning and determine where patients are placed in treatment, and how to provide continuing, integrated care and ongoing service planning.
Cigna Coverage Policies	Documents to assist with decisions about diagnosis, management and treatment in areas of health care.
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.
Clinical Information to Establish Medical Necessity Guideline (EviCore)	Documents that outline medical necessity requirements.
CMS Finalizes Regulatory Definition of Medically “Reasonable and Necessary”	Article describing CMS definition of Medically Reasonable and Necessary.
HM CLN 039: Utilization Management Decisions Appropriate Professional Assessment	The purpose of this policy is to ensure that qualified licensed health professionals assess the clinical information used to make appropriate utilization management decisions. Behavioral Health’s policy requires that appropriately licensed behavioral health professionals assess and supervise utilization management decisions. Only psychologists, addictionologists or board certified psychiatrists are allowed to assess and make medical necessity denial decisions.
HM CLN 040: Utilization Management Guidelines for Utilization Decisions	The purpose of this policy is to describe how Behavioral Health develops, adopts, implements and monitors consistent application of clinical management guidelines used to make utilization decisions.

HM CLN 043: Use and Application of Medical Necessity Criteria Policy	The purpose of this policy is to set forth standards for the use and application of medical necessity criteria when making utilization review coverage decisions pertaining to mental health and substance use disorder levels of care.
HM OPS 023: Emergency Services Policy	Emergency Services are generally covered under the medical plan. Behavioral Health shall cover psychiatric services (including post stabilization) provided in an emergency room by an appropriately licensed clinician without prior authorization.
OPS 37: Medical Director Management Case Review Policy	Establishes a case review process to ensure quality and decision consistency across medical directors for both M/S and MH/SUD.
OPS 48: Healthcare Medical Assessment and Coverage Process for Determination of Medical Necessity Coverage Criteria Recommendations Policy	The purpose of this policy is: • To establish and apply a consistent process in the development of evidence-based Coverage Policies for a wide variety of medical and behavioral technologies; • To ensure national delegated vendor guidelines used to support utilization management decisions are developed with the application of evidence-based principles consistent with Cigna standards, and that the Healthcare Medical Assessment Committee (HMAC) supports and approves applicable vendor guidelines; • To offer a timely and consistent review methodology for medical and behavioral technologies; and • To assist in facilitation of benefit coverage decisions in keeping with evidence-based standards through: • Timely review of relevant peer-reviewed literature and evidence; • Prompt revision of Coverage Policies and other collateral materials with changing technology status, including regularly scheduled reviews of existing Coverage Policies; • A focus on safety, effectiveness, and meaningful clinical outcomes; • Use of a hierarchy of evidence, amongst other variables, to help evaluate the relative strength of the scientific evidence; • Assessing and providing referenced information from published literature and medical expert opinion summaries.
QA 09: Consistency of UM Decision Making Among Medical Directors & Pharmacist (Inter-rater Reliability Policy)	The purpose of this policy and procedure is to provide a quality process for monitoring the consistency of utilization management decision making by Medical Directors and Pharmacists.
UM 12: Qualified Health Professionals Render UM Decisions Policy	The purpose of this policy is to validate licensed professionals supervise and render all levels of utilization management (UM) decisions.
UM 32: Emergency Services Policy	The purpose of this policy is to provide a definition and the process to ensure coverage of emergency services. This policy is provided to demonstrate that emergency services do not require prior authorization
OPS 18 Policy and Procedure Maintenance, Review and Approval Process	The purpose of this policy is to ensure review and dissemination of policies and process within the scope of oversight by the Policy Committee in a timely manner.

OPS 47 Benefit and Coverage Tool Policy	This policy outlines the resources and tools used to assist in making coverage determinations made prospectively (i.e., via precertification or prior to the care), concurrently (i.e., during the care) or retrospectively (i.e., after the care was provided). Use of the resources and tools are categorized by the order of their priority when determining medical and behavioral healthcare coverage.
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Cigna's definition of medical necessity is found in both Cigna and EBH policy documents and applies to all services covered under the plan. Additionally, Cigna's definition of medical necessity aligns with that of the National Committee for Quality Assurance (NCQA).

Cigna delegates utilization management to EviCore for the medical necessity review of M/S services including high tech imaging and cardiology, radiation and medical oncology, musculoskeletal management, spinal procedures, vascular intervention, sleep, molecular labs and gastrointestinal endoscopic procedures.

A separate unrelated entity, American Specialty Health ("ASH"), reviews physical therapy, occupational therapy, massage therapy, acupuncture and chiropractic services on behalf of Cigna Health and Life Insurance Company.

EviCore and American Specialty Health utilize co-branded clinical coverage policies (which Cigna reviews and approves) when performing utilization reviews. The data provided in this NQTL analysis is inclusive of utilization reviews conducted by the above referenced entities.

EviCore and ASH are separate entities who function as delegates for Cigna and as such maintain their own organizational definitions of medical necessity. Upon review, while the definitions are not identical, comparable elements are utilized. When a review is completed, EviCore and ASH are delegates for Cigna and use Cigna's policies and criteria.

All services are subject to medical necessity even if they do not have utilization management protocols applied.

Utilization management review is **not** applicable to the following services for M/S and MH/SUD:

- Emergency: Cigna covers all emergency services, does not require pre-certification of emergency services, nor does it conduct retrospective emergency service medical necessity review or deny emergency service claims absent evidence of fraud.
- Preventive: Cigna covers all preventive services, does not require pre-certification of preventive services, nor does it conduct retrospective preventive service medical necessity review or deny preventive service claims absent evidence of fraud.
- Routine Outpatient Office Visit In-Network and Out-of-Network services are not subject to Medical Necessity determinations.
 - While routine office visits themselves do not require authorization for M/S, some services performed in an office setting may require authorization (e.g. high-tech imaging, outpatient surgery).

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 utilizes the following criteria in its medical necessity determinations:

Benefit Classification	M/S	MH	SUD
Inpatient In-Network	Cigna-Developed supplemented with MCG™	MCG™	The ASAM Criteria®
Inpatient Out-of- Network	Cigna-Developed supplemented with MCG™	MCG™	The ASAM Criteria®
Outpatient In-Network All Other	Cigna-Developed supplemented with MCG™; Co-Branded (ASH, EviCore)	Cigna-Developed (TMS, ABA)	Not Applicable

Outpatient Out-of- Network All Other	Cigna-Developed supplemented with MCG™; Co-Branded (ASH, EviCore)	Cigna-Developed (TMS, ABA)	Not Applicable
Outpatient In-Network Office Visit	N/A – no authorization is required for routine in- network outpatient services	N/A – no authorization is required for routine in- network outpatient services	N/A – no authorization is required for routine in- network outpatient services
Outpatient Out-of- Network Office Visit	N/A – no authorization is required for routine out-of- network outpatient services	N/A – no authorization is required for routine out-of- network outpatient services	N/A – no authorization is required for routine out-of- network outpatient services
Emergency In- Network	N/A - No authorization is required for Emergency Services	N/A - No authorization is required for Emergency Services	N/A - No authorization is required for Emergency Services
Emergency Out-of- Network	N/A - No authorization is required for Emergency Services	N/A - No authorization is required for Emergency Services	N/A - No authorization is required for Emergency Services

Cigna applies the **factors** listed below to assess whether services meet the requirements for medical necessity. In making and determination of the Medical Necessity NQTL there were no additional factors considered and rejected. These factors are applied uniformly and without weighting 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.

Factors	Sources for Each Factor
1. FDA Approval/Clearance	1. As part of the review process, FDA approval or clearance, as appropriate, is necessary, but not sufficient for Cigna to consider a technology, drug, or biologic to be proven. FDA approval or clearance does not apply to all services (i.e., procedures). However, when appropriate and relevant FDA approval or clearance is present, Cigna reviews English language peer-reviewed publications, as well as relevant documents by specialty societies and evidence-based review centers, such as the Agency for Healthcare Research and Quality (AHRQ).
2. Peer Reviewed Evidence/Publication	2. Demonstrated through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or sickness. These include findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes in the Federal Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), National Cancer Institute, National Academy of Sciences, Health Care Financing Administration (HCFA), Congressional Office of Technology Assessment, and any national board recognized by the NIH for the purpose of evaluating the medical value of health services.
3. Clinical Trials and Studies	3. a. A phase I, phase II, phase III or phase IV clinical trial conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition. b. Healthcare Therapeutic Assessment Committee (HTAC) reviews clinical evidence on drug safety, efficacy and information from treatment guidelines from the National Pharmacy and Therapeutics (P&T) Committee process.

In establishing the factors used to determine what services are subject to medical necessity, Cigna considers the following **sources and evidentiary standards**:

Factors	Evidentiary Standards and Applicable Thresholds	Source(s) for Each Evidentiary Standard
1. FDA Approval / Clearance	1. FDA Safety Protocols and regulatory guidance	1. FDA.gov http://www.fda.gov/RegulatoryInformation/Guidances
2. Peer Reviewed Evidence and/or Publication	2. Use of hierarchy of Levels of Scientific Evidence: Level 1: Systematic reviews with or without meta-analysis Level 2: Randomized controlled trial (RCT); observational (analytic) study; cross-sectional study Level 3: Non-consecutive study (i.e., no control group); cohort study; non-randomized controlled cohort study Level 4: Case series; case-control studies Level 5: Literature reviews; consensus reports; expert opinion; professional society/organization recommendations when not based on systematic review/meta-analysis	2. Levels of Evidence Table adapted from the Centre for Evidence Based Medicine, Oxford Centre for Evidence-Based Medicine, 2011: • PubMed® (including MEDLINE®) • Cumulative Index to Nursing & Allied Health Literature (CINAHL) Database (EBSCOHost) • ScienceDirect • Health Business Full Text (EBSCOHost) • EmBase • American Psychological Association PSYCInfo • Web of Science • Academic Search Complete (EBSCOHost) • The Council of Autism Service Providers (CASP) • World Professional Association for Transgender Health (WPATH)
3. Clinical Trials and Studies	3. Safety Protocols Compliance Guidelines Enforcement Activity Clinical Trial phases: • Phase I: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted. • Phase II: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with	3. Clinicaltrials.gov FDA's Role: ClinicalTrials.gov Information FDA • Federally funded trial: The study of investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following: ○ National Institutes of Health (NIH) ○ Centers for Disease Control and Prevention (CDC) ○ Agency for Health Care Research and Quality (AHRQ) ○ Centers for Medicare and Medicaid Services (CMS) ○ A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Department of Veterans Affairs (VA) ○ A qualified non-governmental research entity identified in NIH guidelines for center support grants ANY of the following: ▪ Department of Defense

	similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied. • Phase III: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. • Phase IV: Studies occurring after FDA has approved a drug for marketing. These include post market requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use (National Institutes of Health [NIH], 2021)	▪ Department of Veterans Affairs ▪ Department of Energy if of the following conditions are met: ▫ study or investigation has been reviewed and approved through a system of peer review comparable to the system of peer review of studies and investigations used by the National Institutes of Health ▫ assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review. ▫ The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration. ▫ The study or investigation is a drug trial that is exempt from having such an investigational new drug application
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Step 3: Description of how factors are used in the design and application of the NQTL.

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

- (1) A detailed explanation of how each factor identified and defined in Step 2 is used to determine which MH or SUD benefits and which medical/surgical benefits are subject to the NQTL;
- (2) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how MH or SUD or medical/surgical benefits are subject to the NQTL;
- (3) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualification of each decision maker;

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

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

- (Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.
- (Q2, #6) If the application of the NQTL turns on specific decisions in administration of benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s) [\[Note that this applies to Step 3 in the context of committees/experts that design the NQTL, such as a Pharmacy & Therapeutics Committee or Prior Authorization Committee\]](#).
- (Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.

This FAQ guidance stipulates what plans and issuers should avoid:

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

Issuer Response:

Design and Application:

Exclusions:

All services are subject to medical necessity even if they do not have utilization management protocols applied.

Per the M.C. Dean, Inc. plan certificate language the following are specifically excluded from Mental Health and Substance Use Disorder Services:

- treatment of disorders which have been diagnosed as organic mental disorders associated

with permanent dysfunction of the brain.

- developmental disorders, including but not limited to, developmental reading disorders, developmental arithmetic disorders, developmental language disorders or developmental articulation disorders.
- counseling for activities of an educational nature.
- counseling for borderline intellectual functioning.
- counseling for occupational problems.
- counseling related to consciousness raising.
- vocational or religious counseling.
- I.Q. testing.
- custodial care, including but not limited to geriatric day care.
- psychological testing on children requested by or for a school system.
- occupational/recreational therapy programs even if combined with supportive therapy for age-related cognitive decline.

However, such language is outdated, and plan language/certificates are being updated to reflect the following exclusionary language:

“Non-medical counseling and/or ancillary services, including but not limited to Custodial Services, educational services, vocational counseling, training and rehabilitation services, behavioral training, biofeedback, hypnosis, sleep therapy, return to work services, work hardening programs and driver safety courses.”

These services are excluded because Cigna health plans, consistent with the industry standard, do not cover services that are not medical in nature or not directly medically related. Services that are not medical in nature are not eligible for coverage under a health plan and arguably may not be supported for coverage with pretax dollars. Cigna explicitly cites these services in the plan document to be helpful because customers and clients may ask about whether they are covered. Cigna collected this diverse list of services together in one exclusion solely based on their one common element: each is not medical or not directly medically related in nature.

Clinical Coverage Criteria:

The review and approval of medical necessity clinical coverage criteria is conducted by Cigna's Payment Policy and Coding (PP&C) (formerly Coverage Policy Unit), in partnership with Cigna's Healthcare Medical Assessment Committee (“HMAC”). The PP&C team provides transparent, consistent, industry-standard, and evidence-based guidelines upon which to make coding, reimbursement, and benefit determinations. This team also manages Precertification Policy and Coverage Policy Implementation

Cigna's Healthcare Medical Assessment Committee (“HMAC”) is comprised of licensed clinicians including physicians and nurses from a variety of medical and behavioral disciplines. HMAC also consults with internal Cigna subject matter experts as part of the committee review process. Internal subject matter experts include, but may not be limited to orthopedists, neurologists, neurosurgeons, obstetrician-gynecologists (OBGYNs), oncologists, primary care physicians, internists, surgeons, urologists, pulmonologists, cardiologists and psychiatrists. The committee uses principles of evidence-based medicine in its evaluation of clinical literature, development of its reviews, in its deliberative process, and in preparing published coverage policies.

Title	Qualifications	Years of Experience
Clinical Program Director	RN	10+
Medical Senior Director	Neurology/Sleep	10+
Medical Managing Director	Internal Medicine	10+
Medical Senior Director	Surgery	10+
Medical Principal	Thoracic and Cardiac Surgery, Surgery	10+
Medical Principal	Pediatrics, Internal Medicine, Clinical Genetics and Genomics	10+
Utilization Review Medical Lead	Family Medicine	10+
Utilization Review Medical Principal	Obstetrics and gynecology, Medical Geneticist	10+
Medical Principal	Psychiatry	10+
Medical Director	Psychiatry	10+
Medical Principal	Internal Medicine	10+
Program Management Director	Health Equity Subject Matter Expert	20+
Medical Principal	Internal Medicine	20+

Cigna's HMAc implements an evidence-based medicine approach to rank categories of evidence and assign weight to categories with higher levels of scientific evidence. Additional variables used to evaluate scientific evidence may include study design elements, such as number, power, types of outcomes, comparator intervention, objectiveness of rating tools, and blinding, as well as issues related to conflicts and potential bias of the study authors and institutional associations.

The HMAc develops Clinical Coverage Policies to assist both M/S and MH/SUD medical directors in determining whether a technology is medically necessary, not medically necessary, or experimental, investigational, or unproven, based on an evaluation of peer reviewed, evidence based scientific literature, information from appropriate governing regulatory bodies (e.g. US Food and Drug Administration), and professional society recommendations. All internally developed coverage policies are posted publicly and shared with providers and members upon request. MCG™ Clinical Guidelines and/or ASAM Criteria® Guidelines are also shared upon request. All services under the benefit plan are subject to the plan definition of medical necessity. Cigna does not include any utilization management of emergency or urgent care services for M/S or MH/SUD services; there are no additional criteria or guidelines used.

The Cigna-employed Medical Directors responsible for the development and/or review of medical necessity criteria of M/S and MH/SUD services include:

Coverage Policy Author: The medical professionals who review and draft Clinical Coverage Policies, in consultation with Coverage Policy Subject Matter Experts, as part of the annual clinical review. These recommendations are offered to HMAc for discussion and ultimately require a vote of the

majority to be accepted to go in to affect. The Committee may send it back for further review, reject recommendations, or propose an alternative, or any combination of those outcomes. The committee also discusses relevant health equity concerns.

Coverage Policy Subject Matter Expert: clinical subject matter experts – representing a range of clinical specialties, including, as relevant, MH/SUD experts. HMAc uses the principles of evidence-based medicine in its evaluation of clinical literature, in development of its reviews, in its deliberative process, and in preparing published medical coverage policies. Financial considerations do not drive decisions about medical appropriateness.

As part of the review process, FDA approval or clearance, as appropriate, is necessary, but not sufficient, for Cigna to consider a technology to be proven. FDA approval or clearance does not apply to all services (e.g., procedures). However, when FDA approval or clearance, as appropriate, is present, Cigna reviews English language peer-reviewed publications, as well as relevant documents prepared by specialty societies and evidence-based review centers, such as the Agency for Healthcare Research and Quality (AHRQ). Levels of evidence (referenced below) are assigned to the publications based upon underlying study characteristics, including but not limited to incidence and prevalence of disease, health disparity and health equity factors, study design, number of subjects, clinical outcomes of relevance, statistics used and significance, and assessment of flaws and bias. Consideration of the strength of the evidence includes recognition of a hierarchy of evidence, where increased weight is placed on those studies where the design and characteristics of the study confer a greater degree of statistical certainty between the intervention in a specific patient population, and the clinical outcome. A research team assesses the literature to determine if there is a sufficiently evidence-based proven relationship between the intervention and improved health outcomes. This information is presented to the committee who makes a final determination regarding coverage criteria.

Application of Medical Necessity

When reviewing for medical necessity, Cigna follows a hierarchy of clinical review for both Cigna Healthcare and Evernorth Behavioral Health in the following order per the *Benefit and Coverage Tool Policy (OPS 47)*:

M/S Hierarchy

1. Federal Coverage Mandate (if applicable)
2. State Coverage Mandate (if applicable)
3. Group's Benefit Plan Document (e.g. Group Service Agreement Evidence of Coverage, Certificate of Coverage, Summary Plan Description or similar document)
4. Clinical Coverage Policies (CPs) including Medical Coverage CPs, and Drug CPs and Evernorth Behavioral Health CPs
5. Vendor Partner Co-Branded Guidelines (e.g. EviCore, American Specialty Health)
6. Cigna Coverage Review Department Criteria Manual
7. MCG™
8. Utilization Management Policies and Procedures (such as Network Adequacy, Lack of Information, Continuity of Care and Transition of Care)
9. Administrative Policies
10. Reimbursement and Modifier Policies
11. Medical Inquiry Database

Cigna Healthcare will only supplement Clinical CPs with MCG™ if there is not an established Clinical CP.

MH/SUD Hierarchy

1. Federal Coverage Mandate (if applicable)
2. State Coverage Mandate (if applicable)
3. Group's Benefit Plan Document (e.g. Group Service Agreement Evidence of Coverage, Certificate of Coverage, Summary Plan Description or similar document)
4. Clinical Coverage Policies (CPs) including Medical Coverage CPs, and Drug CPs and Evernorth Behavioral Health CPs
5. The ASAM Criteria®
6. MCG™
7. LOCUS/CALOCUS-CASII, where required by law in California, Colorado, and New York will be applied for mental health coverage determinations.
8. Utilization Management Policies and Procedures (such as Network Adequacy, Lack of Information, Continuity of Care and Transition of Care)
9. Administrative Policies
10. Reimbursement and Modifier Policies
11. Medical Inquiry Database

Evernorth Behavioral Health will only supplement Clinical CPs with MCG™/The ASAM Criteria® if there is not an established Clinical CP.

Review of the application of Clinical Criteria. (Clinical judgement)

Clinical reviews of MH/SUD and M/S services are performed by clinicians with comparable expertise in MH/SUD treatment and M/S treatment, respectively. Clinical information submitted by providers in connection with MH/SUD reviews that may be denied are reviewed by MH/SUD experts to the same extent M/S experts review coverage requests for M/S services. Individuals who issue approvals may be nurses or care managers (licensed behavioral clinicians) as accreditation standards do not dictate that approvals be issued by peer reviewers. The prompts for a clinical review by an appropriately licensed clinical expert – namely, the identification of a potential denial – are identical across MH/SUD and M/S benefits. For both M/S and MH/SUD only a physician or peer reviewer can issue a medical necessity denial. If the enrollee's treating provider is a psychiatrist, then a psychiatrist may issue an adverse benefit determination because he/she is a peer reviewer of the treating provider.

When Evernorth does not have a medical director available to meet the timing needs for the review, Prest & Associates LLC ("Prest") is used. Prest is the oldest and one of the largest independent review organizations specializing in psychiatry, addiction medicine, and behavioral healthcare. They are Utilization Review Accreditation Commission (URAC) accredited. Prest has over two decades of experience and provides medical necessity and appropriateness of care review for health plans, insurers, government agencies, and other clients. For Evernorth, Prest's initial MH/SUD reviews and Level 1 appeals are consultations, with Evernorth's internal Medical Directors making the final determinations.

To ensure consistency in the application of Medical Necessity Clinical Criteria, Cigna conducts Inter-

Rater Reliability (IRR) testing for both M/S and MH/SUD reviewers. In addition to evaluating the consistency of clinical decision-making across reviewers, IRR process is used to identify any potential revisions to the Clinical Coverage Policies that may be warranted. IRR reviews are conducted according to accreditation standards and are intended to ensure consistency in decision-making across reviewers making medical necessity determinations.

Cigna uses the same factors, sources and evidentiary standards applicable to the medical necessity NQTL for the medical necessity appeals. For internal appeals, Cigna follows a two-level internal appeal process for resolving disputes regarding pre/post-service benefit coverage and medical necessity denials. For medical necessity reviews, a second health care professional, not involved in any previous decision or subordinate of the individual in the previous decision, performs a two-level appeal, whether expedited or standard.

For external appeals, Cigna informs customers of their right to request an external appeal to an Independent Review Organization (IRO), at no cost to the Customer for both M/S and MH/SUD external appeals in the final determination letter. The communication provides the customer with all information regarding the right of appeal, applicable time limitations and specific instructions on the initiation of an appeal by the Customer or the Customer's designate. The National Appeals Organization will facilitate the appeal through program information and IRO program description. (**note: state specifics will always take precedence*)

All records and materials relevant to the adverse determination and included in the previous appeal files are presented for review to the IRO. New information and documentation submitted with the external review request is forwarded to the IRO to consider. The decision of the IRO is final and is binding on us and the plan. Relevant portions of the Customer's contract (e.g., Certificate of Coverage, Summary Plan Description) are included in the materials for external review. The IRO will render a decision without deference to the previous decisions.

Clinical Criteria Co-branded with a Delegated Vendor

Where Cigna delegates utilization management functions to an affiliate or vendor/delegate, the aforementioned Cigna entities must adhere to Cigna's policies and procedures:

- **American Specialty Health (ASH)** reviews: physical therapy, occupational therapy, massage therapy, acupuncture and chiropractic services.
- **EviCore** reviews: high tech imaging and cardiology, radiation and medical oncology, musculoskeletal management, spinal procedures, vascular intervention, sleep, molecular labs and gastrointestinal endoscopic procedures.

Cigna maintains the *QA 02 Delegation Policy* and Quality Programs to ensure its delegates are adhering to Cigna's policies and procedures when performing utilization review. The following quality activities are in place to ensure effective monitoring and ongoing adherence to the quality and accreditation requirements established by the program:

- A formal audit of the delegated entity is performed utilizing comprehensive audit tools, which incorporate accreditation, regulatory, and Cigna specific standards.
- Prior to approval of delegation a thorough pre-delegation audit is performed. Audits are then performed annually or more frequently thereafter as warranted.
- Ongoing review and analysis of key performance indicators are performed to monitor ongoing

compliance to established benchmarks. These metrics include a comprehensive list of inpatient and outpatient utilization statistics.

- Active management of corrective action plans for any opportunities identified through delegation oversight process.
- Multi-departmental leadership oversight and monitoring of the delegation oversight programs is approved through the appropriate committee. The committee process includes reviewing and approving the annual program delegation documents and reports.
- Joint Operational Committee, which includes Cigna and the delegate, that meet to collaborate and communicate effective tools and to provide feedback to support the delegation process.
- Regular reporting through standardized committees

Clinical Criteria Review, Maintenance, and Application

All Clinical Criteria, including MCG™, ASAM Criteria®, Cigna-Developed, Cigna Co-branded are subject to annual review but may be reviewed more frequently when there are new, compelling clinical data or business factors that require it. Additionally, Clinical Criteria may be retired and archived when Cigna determines there is no longer a business or clinical need to maintain such Clinical Criteria. Archived Clinical Criteria are maintained as required by Cigna's Global Records Management Policy.

Review of Cigna's Clinical Coverage Policies and vendor guidelines may also be prompted by feedback received through multiple channels including the provider community, customers, frontline reviewers, Payment Policy and Coding (PP&C) (formerly Coverage Policy Unit) and the impetus of new, emerging and evolving technologies. Clinical criteria may be updated as needed to reflect current patterns of care. Input and suggestions are actively invited and sought from stakeholders, such as community physicians, primary care providers and behavioral health practitioners.

Only a single approved Coverage Policy, Guideline, or Criteria is utilized to review a specific service as outlined in the hierarchy provided above. Meaning, Cigna will not interchange or combine criteria when completing a medical necessity review. There are no duplicative Clinical Criteria, or a Clinical Criteria selection process. The Medical Necessity Clinical Criteria applied to a service is one of Cigna-developed, Cigna-co branded, MCG™ or ASAM. In the application of Medical Necessity Clinical Criteria appropriate documentation including applicable clinical information (i.e.: diagnosis, current symptoms, reason for admission, level of functioning and functional impairments, treatment history and current treatment, medications, medical concerns, etc.) must be documented for the application of Medical Necessity Clinical Criteria to the level of care requested and to make an appropriate level of care determination based on the clinical presentation and clinical judgement.

Comparability in process is evidenced in the plan's coordinated process of reviewing and managing M/S and MH/SUD criteria.

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:

Consistent with the above-stated medical necessity definition, sources Cigna utilizes to evaluate Medical Necessity include its own internally developed [Clinical Coverage Policies](#) (medical necessity criteria) and the [MCG™ Guidelines](#) when conducting medical necessity reviews of M/S services, procedures, devices, equipment, imaging, diagnostic interventions; its own internally developed Clinical Coverage Policies and the MCG™ Care Guidelines when conducting medical necessity reviews of MH services and technologies; and [“The ASAM Criteria®”](#) when conducting medical necessity reviews of SUD services and technologies. All of these referenced sources are clinical criteria, which are rules or standards on which a medical necessity decision or judgment is based.

The various guidelines for clinical criteria/medical necessity (both external and internal) do not overlap and there is no hierarchical weight assigned to the standard, source, or guideline in any given review for clinical criteria. In other words, where a specific Cigna medical policy applies, that medical policy applies in whole without regard to other more general guidelines, like The ASAM Criteria® or MCG™ Guidelines as outlined in Cigna's *Utilization Management Guidelines (HM CLN 040)*.

HMAC utilizes the following process in their evaluation of evidence. The overall strength of evidence reflects recognition of the hierarchy of evidence, with greater weight assigned to study designs that provide higher confidence in the relationship between the intervention and meaningful clinical outcomes in a defined patient population.

Coverage Policy Development

A lack of statistically significant evidence demonstrating improved health outcomes does not, by itself, establish inappropriate care, but may indicate uncertainty or variability in clinical effectiveness that warrants utilization management oversight. Cigna's Healthcare Medical Assessment Committee implements an evidence-based medicine approach to rank categories of evidence and assign weight to categories with higher levels of scientific evidence as set forth below in Cigna's "Levels of Scientific Evidence" table, adapted from the Oxford Centre for Evidence-Based Medicine, 2011:

Level 1: Systematic reviews with or without meta-analysis

Level 2: Randomized controlled trial (RCT); observational (analytic) study; cross-sectional study

Level 3: Non-consecutive study (i.e., no control group); cohort study; non-randomized controlled cohort study

Level 4: Case series; case-control studies

Level 5: Literature reviews; consensus reports; expert opinion; professional society/organization recommendations when not based on systematic review/meta-analysis

Following completion of the evidence assessment, findings are presented to the appropriate committee. The committee considers whether the observed variation represents sufficient concern regarding appropriateness, consistency, or value of care to support inclusion of the service on the Master Precertification List. Final determinations regarding coverage criteria are made through the established committee review process.

Additional variables used to evaluate the relative weight of scientific evidence may include study design elements such as number, power, types of outcomes, comparator intervention, objectiveness of rating tools, blinding, etc.; as well as issues related to conflicts and potential bias of the study authors, source of funding and institutional associations.

Cigna considers other sources of internal and external information as part of its decision-making process. For instance, Cigna welcomes input from health care professionals and other interested parties which is then evaluated for inclusion in the Coverage Policy. Health care professionals may share their comments with the regional market medical executive representing a specific geography, account, or subject matter issue. The information is reviewed, usually as part of the annual update process.

Medical Inquiry

Where there is no coverage policy, Cigna will assign an inquiry to the Medical Inquiry Unit. The team is staffed by authors who are Registered Nurses with oversight from a Senior Medical director. The authors will conduct an evidence-based review and make recommendations about coverage. The function of the inquiry is to assist the physician reviewer in considering the clinical appropriateness of the specific clinical request in question. Inquiry requests are reviewed periodically by HMAC to determine if a coverage policy should be considered for development. A summary of the evidence or lack thereof is presented to HMAC who will make a final determination.

The inquiry review is based on a search of the body of knowledge available, relevant to the technology in question, and includes specific citations from appropriate sources used in research, which include the following:

- peer-reviewed scientific studies published in journals that meet nationally recognized requirements for scientific manuscripts.
- standard medical reference compendia and authoritative medical textbooks
- findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes in the federal Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), National Cancer Institute, National Academy of Sciences, Health Care Financing Administration (HCFA), Congressional Office of Technology Assessment, and any national board recognized by the NIH for the purpose of evaluating the medical value of health services.

Procured Coverage Policy Guidelines

MCG™

Cigna has utilized MCG™ Clinical Criteria in M/S decisions for over 20 years. In November 2020 Cigna chose to also use MCG™ for MH Clinical Criteria, specifically to ensure that the process for development and updates of Clinical Criteria would be consistent with, and comparable to, the clinical criteria used for M/S benefits. Additionally, MCG™'s development of MH Clinical Criteria extensively references literature from the following non-profit organizations and publications:

- American Society of Addiction Medicine (The ASAM Criteria®)
- Early Childhood Service Intensity Instrument (ECSII)
- American Psychiatric Association
- American Academy of Child and Adolescent Psychiatry
- American Association of Community Psychiatrists
- Association for Ambulatory Behavioral Healthcare

Cigna uses MCG™ Health Guidelines (Clinical Criteria) for ambulatory care, inpatient and surgical care, recovery facility care, home care, and behavioral health care for the application of Medical Necessity when there are no Cigna developed or co-branded Clinical Criteria and Cigna has determined additional Criteria is not warranted. In its selection of MCG™, Cigna ensured that the same process of evidence-based review used in internal development process including use of the hierarchy of evidence (which is a nationally recognized standard), consideration of external professional society, provider and independent evidence-based organizations are used as part of the MCG™ Health Clinical Criteria development method.

MCG™ clinical editors analyze and classify peer-reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence-based medicine. Annually, thousands of references are reviewed and ranked, with unique citations. MCG™ combines clinical guidelines, created from an unbiased review of the most current literature and data, with innovative software solutions and robust analytics. On an annual basis, MCG™ Health ensures that each guideline undergoes external review by clinically active experts (e.g., board-certified specialist physicians without stated financial conflicts of interest) to confirm the clinical appropriateness, accuracy, validity, and applicability of each guideline. An MCG™ supervising clinical editor evaluates all comments from these external reviewers and makes necessary changes to the guideline. Updated and new MCG™ Health guidelines are presented to Cigna's HMA Committee annually. Following a review and discussion of the changes and new guidelines, the HMA votes to approve and implement the proposed changes to the MCG™ Clinical Criteria, or the addition of the new Clinical Criteria set. Alternatively, HMA may choose to supplement MCG™ Clinical Criteria with Cigna-Developed Clinical Criteria. Upon approval and finalization, MCG™

Clinical Criteria is integrated into Cigna's medical management platform for seamless clinical workflow.

The ASAM Criteria®

Cigna has adopted The ASAM Criteria®, developed and published by the American Society of Addiction Medicine, as its sole criteria for substance use disorder benefit determinations. Due to the mandates implemented by numerous states, The ASAM Criteria® has been established as the national standard for SUD treatment. The states recognize The ASAM Criteria® as flexible and transparent with accepted standards of care for SUD treatment. The ASAM Criteria® are objective guidelines that help clinicians standardize treatment planning and determine where patients are placed in treatment, and how to provide continuing, integrated care and ongoing service planning. The ASAM Criteria® are also useful in supporting appropriate utilization review decisions. Cigna ensures that the same process of evidence-based review used in its internally developed coverage policy process are used as part of The ASAM Criteria® development. This includes use of the hierarchy of evidence, consideration of external professional society guidelines, and independent evidence-based organizations. The ASAM Criteria® is continually reviewed and revised through collaboration between ASAM leadership and the Steering Committee of the Coalition for National Clinical Criteria.

The ASAM Criteria® was built on a foundation of evidence around the multidimensional factors that influence disease severity and prognosis and expert consensus from a broad coalition of clinical stakeholders. Found in the methodology for the 4th Edition of The ASAM Criteria®. Revisions to ASAM Clinical Criteria are led by the Criteria Editorial Team with oversight from ASAM's Criteria Strategy Steering Committee, Quality Improvement Council and Board of Directors. The Coalition for National Clinical Criteria provides input throughout the process. The Coalition represents major stakeholders in addiction treatment and has been meeting regularly since the development of the first ASAM Patient Placement Criteria in 1991. The coalition addresses feedback and ensures that the Criteria adequately serves and supports the needs of the addiction treatment field.

ASAM conducts literature review and stakeholder feedback to review and inform Clinical Criteria. Structured literature reviews are used to inform updates to The ASAM Criteria®. For each review ASAM staff conducts a brief literature search to determine the appropriate scope of the literature review based on whether the inquiry is subject to systematic reviews or not and whether there is unlikely to be direct research evidence (e.g., staffing ratios). Review groups are comprised of at least three experts in the specific topic. The ASAM Criteria® conducted a full review of criteria in 2013; ASAM process and development is included in its 4th Edition.

Criteria Development and Adoption:

Policy OPS_48: Healthcare Medical Assessment and Coverage Process for Determination of Medical Necessity Coverage Criteria Recommendations outlines how Cigna's Payment Policy and Coding (PP&C) (formerly Coverage Policy Unit), in partnership with Cigna's Healthcare Medical Assessment Committee (HMAC), conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical/behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals. Cigna maintains one policy applicable to Cigna Healthcare (M/S) and Evernorth Behavioral Health (MH/SUD) that outlines the requirements for a consistent process in the development of evidence-based coverage policies for a wide variety of medical technologies.

M/S	MH/SUD
OPS 48 Healthcare Medical Assessment and Coverage Process for Determination of Medical Necessity Coverage Criteria Recommendations	OPS 48 Healthcare Medical Assessment and Coverage Process for Determination of Medical Necessity Coverage Criteria Recommendations
The purpose of this policy is: • To establish and apply a consistent process in the development of evidence-based Coverage Policies for a wide variety of medical and behavioral technologies; • To ensure national delegated vendor guidelines used to support utilization management decisions are developed with the application of evidence-based principles consistent with Cigna standards, and that the Healthcare Medical Assessment Committee (HMAC) supports and approves applicable vendor guidelines; • To offer a timely and consistent review methodology for medical and behavioral technologies; and • To assist in facilitation of benefit coverage decisions in keeping with evidence-based standards through: ○ Timely review of relevant peer-reviewed literature and evidence; ○ Prompt revision of Coverage Policies and other collateral materials with changing technology status, including regularly scheduled reviews of existing Coverage Policies; ○ A focus on safety, effectiveness, and meaningful clinical outcomes; ○ Use of a hierarchy of evidence, amongst other variables, to help evaluate the relative strength of the scientific evidence; ○ Assessing and providing referenced information from published literature and medical expert opinion summaries.	

Definition of Medical Necessity and application of Clinical Criteria comparative analysis in writing.

Cigna maintains operational policies applicable to M/S only, operational policies applicable to MH/SUD only and operational policies applicable to both. In its policy review, Cigna created a policy crosswalk for business level process alignment of operational policies governing the application of medical necessity and the development of Clinical Criteria.

Development of Clinical Criteria comparative analysis in writing.

To ensure that Cigna's policies are consistently applied, Cigna conducts a thorough review of policies and procedures at least annually. The review includes an analysis of applicable M/S and MH/SUD policies and procedures to identify potential gaps or inconsistencies. Cigna is providing the below examples of Utilization Management policies used in the application of medical necessity to demonstrate comparability and consistency. As described in policy *OPS-18 Policy and Procedure Maintenance, Review and Approval Process*, these Cigna policies were developed and reviewed according to URAC and NCQA standards, and regulatory requirements.

Cigna's *Medical Director Management Case Review Policy (OPS 37)* establishes the regular occurring case review process to ensure quality decision consistency across the M/S and MH/SUD Physicians Operation Team.

M/S	MH/SUD
OPS 37 Medical Director Management Case Review Policy	OPS 37 Medical Director Management Case Review Policy
The purpose of this policy is to establish a case review process to ensure quality and decision consistency across Medical Directors. This includes a process for handling mechanisms to effectively measure and monitor case reviews against standard policy and procedures. This promotes communication, and coaching sessions between supervisor and employee, when necessary, to drive improved quality and clinical outcomes for the customer,	

and to identify group and individual improvement opportunities. The objective of the policy is to promote superior clinical outcomes.

The Medical Director case review process is completed quarterly to assure the Medical Directors are following established policies and procedures, as well as quality standards. The case review process provides individual and /or aggregate case level outcomes. The aggregate case review results are reported quarterly to the appropriate national quality committees. Analyses of trends result in quality improvement action plans.

Cigna's Qualified Health Professionals Render UM Decisions (UM 12) and *Evernorth's Utilization Management Decisions – Appropriate Professional Assessment (HM CLN 039)*, establish the process to validate licensed professionals (qualified health professionals) who assess the clinical information used to support UM decisions and establishing the ability of non-clinical staff to provide assistance through the performance of administrative tasks.

These reviewers are clinicians employed by Cigna to conduct utilization reviews with the treating provider.

M/S	MH/SUD
UM 12 Qualified Health Professionals Render UM Decisions	HM CLN 039 Utilization Management Decisions – Appropriate Professional Assessment
The purpose of this policy is to validate licensed professionals supervise and render all levels of utilization management (UM) decisions. Qualified health professionals assess the clinical information used to support UM decisions. Non-clinical staff may provide assistance by performing administrative tasks only. RN's provides clinical oversight to non-clinical and LPN/LVN staff and/or reviews inpatient and outpatient UM services using established, approved, medical criteria, tools and references as well as own clinical training and education in making medical necessity coverage "approval" decisions. RN staff includes Inpatient Case Manager (IPCM) and Pre-service/Post Service Utilization Review Nurse (UM) roles. Licensed Physician (i.e. Medical Director) – provides clinical oversight to pharmacist staff where indicated, nurse staff and makes medical necessity UM decisions using evidence-based medical necessity guidelines, new technologies information and board-certified specialty (same or similar) consultants for additional medical expertise as required as well as own clinical training and education in making medical necessity coverage decisions. Medical Directors: Medical Director qualification requirements include: • Hold an active unrestricted license or certification to practice medicine in a state or territory of the United States • Unless expressly allowed by state or federal regulations, are located in a state or territory of the United States when conducting a peer clinical review • Are qualified as determined by the Senior Medical	The purpose of this policy is to ensure that qualified licensed health professionals assess the clinical information used to make appropriate utilization management decisions. Behavioral Health's policy requires that appropriately licensed behavioral health professionals assess and supervise utilization management decisions. Only psychologists, addictionologists or board-certified psychiatrists are allowed to assess and make medical necessity denial decisions. Care managers collect data for pre-service, concurrent, and post-service utilization decisions and have the authority to approve but not to deny medical necessity services. In the event that a care manager cannot approve the utilization request, the case is forwarded to an appropriate peer reviewer for assessment and the decision to approve or deny services. Medical Directors: Behavioral Peer Reviewers are Board Certified Psychiatrists, Licensed Clinical Psychologists and Certified Addictionologists who may have the following job titles: • Senior Medical Director • Medical Officer • Medical Director • Medical Principal Qualifications: • Board certified psychiatrist,

Director to render a clinical opinion about the medical condition, procedure and treatment under review • Hold a current and valid license in the same category as the ordering provider or as a Doctor of Medicine, or as a Doctor of Osteopathic Medicine. Medical Director Areas of Responsibility for UM Decisions; includes, but not limited to the following: • Review and render all medical necessity denials. • Make medical necessity decisions in accordance with state licensure requirements as applicable. • Provide specific reason(s) for denials in case documentation and letter content. • Provide oversight and ongoing consultation to clinical and non-clinical staff. • Complete ongoing education to maintain licensure and update professional skills.	addictionologists, or doctoral level psychologists with current unrestricted license in the United States or its territories. Responsibilities include: • Conducting Pre-service reviews • Concurrent reviews • Post-service reviews • Medical necessity determinations including: ○ Approvals ○ Denials
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In application, for both MH/SUD and M/S medical necessity decisions, the reviewer rendering an adverse benefit determination based on medical necessity must be similarly licensed to the enrollee's treating provider. If the enrollee's treating provider is a psychiatrist, for example, then a psychiatrist must issue the adverse benefit determination.

Clinical reviews of MH/SUD and M/S services are performed by clinicians with comparable expertise in MH/SUD treatment and M/S treatment, respectively, such that clinical information submitted by providers in connection with MH/SUD reviews that may be denied are reviewed by MH/SUD experts to the same extent M/S experts review coverage requests for M/S services. Individuals responsible for denying either a MH/SUD or M/S review request must be considered "peer reviewers," that is, must hold a similar license as the customer's treating provider. Individuals who issue approvals may be nurses or case managers, as accreditation standards do not dictate that approvals be issued by peer reviewers. The reasons for a clinical review by an appropriate clinical expert – namely, the identification of a potential denial – are identical across MH/SUD and M/S benefits.

As noted in step 1, All services are subject to medical necessity even if they do not have utilization management protocols applied.

Cigna covers all emergency services, does not require pre-certification of emergency services, nor does it conduct retrospective emergency service medical necessity review or deny emergency service claims absent evidence of fraud.

Review of *UM-32: Emergency Services in comparison with HM-OPS-023: Emergency Services* reflects prior authorization not required for emergency services.

M/S	MH/SUD
UM-32: Emergency Services	HM-OPS-023: Emergency Services
Cigna HealthCare covers all emergency services, does not require pre-certification of emergency services, nor does it conduct retrospective emergency service medical necessity review or deny emergency service claims absent evidence of fraud.	Behavioral Health shall not require prior authorization for any emergency stabilization services believed to be required for an emergent need and shall cover emergency services provided to individuals under the plan. This includes emergency claims submitted by a healthcare professional, facility, an individual or their representative within or outside

	of the defined service area as part of pre-service, concurrent, or retrospective/post service reviews.
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In application, both policies ensure coverage without imposing prior authorization or pre-certification requirements. In each case, emergency services are covered broadly and consistently—without retrospective medical necessity review or denial absent fraud—regardless of whether the claim is reviewed pre-service, concurrent, or post-service, or whether services are provided inside or outside the service area.

A review of Cigna’s written policies and processes reveals the comparable application of medical necessity to M/S and MH/SUD services within the applicable benefit classifications. Cigna's medical necessity coverage policy development and application process is consistent between M/S and MH/SUD. Cigna applies comparable evidence-based guidelines to define established standards of effective care in both M/S and MH/SUD benefits.

Cigna has identified language variations in operational policies between MH/SUD and M/S benefits, however in application such language variations do not present a comparability or stringency problem within the context of the NQTL requirement as the intent and application is the same. Instances where Cigna noted a variation between the process of administering MH/SUD and M/S benefits, specifically Cigna’s peer-to-peer variation do not present a stringency issue as the variation in process is *more* advantageous to the administration of MH/SUD benefits than M/S benefits.

Step 5: Demonstration of comparability and stringency in operation.

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

- (1) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH or SUD benefits in a classification are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards or other factors used in designing and applying the NQTL with respect to medical/surgical benefits, including:
 - (A) An explanation of any methodology or underlying data used to demonstrate the application of the NQTL, in operation;
 - (B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the MH or SUD benefits and medical/surgical benefits to which the NQTL is applicable;
 - (C) With respect to an NQTL for which relevant data is temporarily unavailable as

described in Section 146.136(c)(4)(iii)(A)(3)(i) a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

- (D) With respect to an NQTL for which no data exist that can reasonably assess any relevant impact of the NQTL on relevant outcomes related to access to MH and SUD benefits and medical/surgical benefits as described in Section 146.136(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the BQTL's impact, an explanation of why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the NQTL complies with Section 146.136(c)(4)(iii)(A);
- (2) Identification of the relevant data collected and evaluated, as required under Section 146.136(c)(4)(iii)(A);
- (3) Documentation of the outcomes that resulted from the application of the NQTL to MH or SUD benefits and medical/surgical benefits, including:
 - (A) The evaluation of relevant data as required by Section 146.136(c)(4)(iii)(A);
 - (B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the NQTL contributes to material differences in access to MH or SUD benefits as compared to medical/surgical benefits, in accordance with Section 146.136(c)(4)(iii)(B)(2);
- (4) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii), including:
 - (A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to MH or SUD benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the NQTL; and
 - (B) To the extent differences in access to MH or SUD benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate MH and SUD benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply an NQTL, documentation explaining how any such differences are attributable to those standards or measures, as required by Section 146.136(c)(4)(iii)(B)(2)(ii); and

- (5) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to MH or SUD benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under Section 146.136(c)(4)(iii)(B)(1) to address material differences to comply, in operation with Section 146.136(c)(4), including as applicable:
- (A) A reasoned explanation of any material differences in access to MH or SUD benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and
- (B) For a plan or issuer designing and applying one or more NQTLs related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network MH and SUD benefits as compared to in-network medical/surgical benefits, including those listed in 146.136(c)(4)(iii)(C).

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

- (Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.
- (Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).
- (Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.
This FAQ guidance stipulates what plans and issuers should avoid:
- (Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.
- (Q3, # 2) Conclusory or generalized statements, including mere recitations of the legal standard, without specific supporting evidence and detailed explanations.
- (Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.
- (Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Issuer Response:

In Operation:

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

Behavioral Health’s (EBH) “Utilization Management Guidelines for Utilization Decisions policy (HM CLN 040) and HM CLN 043: Use and Application of Medical Necessity Criteria Policy and Cigna’s Consistency of Utilization Management Decision Making Among Medical Directors & Pharmacists (Inter-rater Reliability) (QA 09) policy which outline how Cigna develops, adopts, implements and monitors consistent application of medical necessity requirements.

In doing so, Cigna has evaluated documentation standards, demographic, and clinical information required to render a medical necessity determination. In the application of the Medical Necessity NQTL, similar documentation is required. Both the M/S and MH/SUD teams adhere to similar minimum medical necessity documentation standards.

For medical necessity determinations and the application of Clinical Criteria of:

- M/S services: the clinical teams collect diagnosis(es), requested service, level of care, provider network status, customer eligibility status, and relevant clinical information.
- MH/SUD services: care managers collect and document diagnosis/treatment information, diagnosis, proposed treatments or procedures, proposed admission or services date(s) and relevant clinical information

Cigna monitors utilization management data to evaluate and trend various measures, including:

- Service volumes
- Level of care utilization
- In-Network and Out-of-Network variances

2025 Virginia Book of Business Data

In-Network Inpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	366		2,701	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	5	1.37%	356	13.18%

Out-of-Network Inpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	149		28	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	6	4.03%	9	32.14%

In-Network All Other Outpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	68		20,267	

Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	1	1.47%	3,010	14.85%
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In-Network Outpatient Office	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	0		705	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	0	0.00%	97	13.76%

Out-of-Network All Other Outpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	26		668	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	7	26.92%	216	32.33%

Out-of-Network Outpatient Office	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	2		82	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	0	0.00%	13	15.85%

*Routine office visits do not require authorization for M/S or MH/SUD. However, certain M/S services performed in an office setting, such as high-tech imaging and outpatient surgery, may require authorization. Therefore, the reported M/S volume includes Network Exception Requests (NERs) and authorization requests for these services.

The above data illustrates a lower MH/SUD medical necessity denial rate across in and out of network, inpatient and outpatient benefit classifications.

2025 Cigna Commercial Book of Business Data

In-Network Inpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	87,518		750,948	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	1,868	2.13%	104,843	13.96%

Out-of-Network Inpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	48,207		3,744	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	1,984	4.12%	739	19.74%

In-Network All Other Outpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	23,266		4,601,820	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	3,190	13.71%	596,742	12.97%

In-Network Outpatient Office	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	0		201,749*	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	0	0.00%	26,496	13.13%

Out-of-Network All Other Outpatient	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	7,366		126,563	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	1,848	25.01%	34,874	27.55%

Out-of-Network Outpatient Office	MH/SUD	MH/SUD Medical Necessity Denial Rate	M/S	M/S Medical Necessity Denial Rate
Total Requests (Prior Auth, Concurrent, Retro)	9,995*		32,363*	
Total Medical Necessity Denials (Prior Auth, Concurrent, Retro)	982	9.82%	6,237	19.27%

*Routine office visits do not require authorization for M/S or MH/SUD. However, certain M/S services performed in an office setting, such as high-tech imaging and outpatient surgery, may require authorization. Therefore, the reported M/S volume includes Network Exception Requests (NERs) and authorization requests for these services, while the MH/SUD volume reflects NERs only.

The above data illustrates a lower MH/SUD medical necessity denial rate across in and out of network, inpatient and outpatient benefit classifications except for in-network all other outpatient. For the in-network all other outpatient classification, the MH/SUD and M/S denial rates were comparable (13.71% vs. 12.97%). The 0.74 percentage point difference is small, and the MH/SUD rate is based on a materially smaller denominator of requests than the M/S rate (23,266 vs. 4,601,820), which makes the MH/SUD rate more sensitive to variation. Accordingly, this difference does not, by itself, indicate more stringent application of the NQTL to MH/SUD benefits.

Inter Rater Reliability (IRR)

As a part of the “in operation” analysis, Cigna conducts routine IRR exercises (occurring no less frequently than annually) which are used to evaluate the consistency of clinical decision-making across reviewers and to identify the need for any potential revisions to coverage policies. IRR reviews are conducted according to accreditation standards.

Cigna's most recent MH/SUD and M/S IRR exercise revealed substantial agreement across reviewers who participated in the assessment and did not reveal a need to revise any coverage policies. These results for MH/SUD and M/S benefits show comparability and equivalent stringency in the process of performing medical necessity reviews.

2025 IRR Results			
	MH/SUD Cases	M/S Cases	Pharmacy Cases
Review 1	100%	100%	100%
Review 2	100%	100%	100%

Both M/S and MH/SUD have a concordance rate expectation of 90% as required by multiple state regulations. Any staff that did not pass their initial attempt received additional training/remediation. Please note, prior to 2025 M/S had a concordance rate expectation of 80%.

Cigna's IRR process demonstrates Cigna's diligence in monitoring the comparability of MH/SUD and M/S medical necessity application.

Cigna routinely reviews utilization management data to evaluate and ensure operational compliance of the NQTL. Classification and sub-classification data and calculation of denial rates are measured for comparability. Cigna's application of the medical necessity NQTL, specifically approval and denial rates, for Prior Authorization, Retrospective Review, and Concurrent Review across benefit classifications revealed no significant discrepancies in medical necessity denial rates between MH/SUD and M/S benefits.

While operational outcomes alone are not indicative of NQTL compliance, comparable outcomes can help support compliance with the utilization of the "in operation" component.

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:

Cigna has identified that the medical necessity definition is consistent for both M/S and MH/SUD. All services under the benefit plan are subject to the plan definition of medical necessity. Cigna does not include any utilization management of emergency or urgent care services for M/S or behavioral health services.

Cigna considers the same factors, sources, and evidentiary standards for both M/S and MH/SUD in determining services to which medical necessity will apply.

As written, both M/S and MH/SUD apply consistent methodology for the development and selection of its M/S and MH/SUD Clinical Coverage Policies, Guidelines, and Criteria. In operation, the data shows lower medical necessity denial rates across MH/SUD as compared to M/S with the exception of in-network outpatient all other with less than a 1% difference. Additionally, M/S and MH/SUD both conduct Inter-Rater Reliability exercises to evaluate the consistency of clinical decision-making across reviewers and to identify the need for any potential revisions to coverage policies; IRR exercise results show M/S and MH/SUD consistently applying medical necessity.

Based upon its analysis, Cigna has concluded that the processes, strategies, evidentiary standards, and other factors used to determine MH/SUD services subject to medical necessity requirements are comparable to, and no more stringent than those used for the M/S services in all benefit classifications.

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

Mental Health Parity Legal Team including:

Managing Counsel;
Associate Senior Counsel; and
Counsel

Mental Health Parity Compliance team including:

Legal Compliance Senior Manager;
Legal Compliance Senior Advisor

M/S and MH/SUD subject matter experts including:

Medical Managing Director Evernorth Behavioral Health
Program Management Senior Manager;
Medical Senior Principal;
Legal Compliance Advisor