

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.

Services Subject to Experimental, Investigational, Unproven (EIU)

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 Experimental, Investigation, or Unproven (EIU) services applied to mental health/substance use disorder ("MH/SUD") and/or medical/surgical ("M/S") services and is incorporated in plans insured by Cigna Health and Life Insurance Company ("CHLIC").

EIU services are generally defined as a treatment, procedure, facility, type of equipment, drug, service, or supply ("intervention") that has been determined not to be medically effective for the condition being treated. In the review and analysis of the Services Subject to Experimental, Investigational, or Unproven NQTL, Cigna reviewed policies applicable to Cigna and Evernorth Behavioral Health (EBH), Delegated Vendor(s), and Connect Bronze 6500 Indiv Med Deductible 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.

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

Connect Bronze 6500 Indiv Med Deductible Plan Language
Experimental / Investigational / Unproven Procedures: a drug, device or medical treatment or procedure is considered Experimental or Investigational or Unproven if: ▪ it has not been demonstrated through existing peer-reviewed, evidence-based scientific literature to be safe and effective for treating or evaluating the condition or illness for which it is proposed; or ▪ it has not been given approval for marketing by the United States Food and Drug Administration at the time it is furnished and such approval is required by law; or ▪ reliable evidence shows it is the subject of ongoing phase I, II, III or IV clinical trials or understudy to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with the current standard of treatment or diagnosis, except for an Insured Person's costs incurred during clinical trials for cancer; or ▪ reliable evidence shows that the consensus of opinion among experts is that further studies or clinical

trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with the standard means of treatment or diagnosis.

Reliable evidence means only: the published reports and articles in authoritative, peer-reviewed medical and scientific literature; written protocol or protocols by the treating facility or other facilities studying substantially the same drug, device or medical treatment or procedure; or the medical informed consent used by the treating facility or other facilities studying substantially the same drug, device or medical treatment or procedure.¹

Excluded Services

In addition to any other exclusions and limitations described in this Policy, there are no benefits provided for the following:

Services or supplies that are considered to be for Experimental Procedures or Investigational Procedures or Unproven Procedures, except as otherwise stated in this Policy under "Clinical Trials."²

Glossary:

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. Independent Review Organization (IRO)/Review Organization: acts as a third-party medical review resource which provides objective, unbiased medical determinations that support effective decision making, based only on medical evidence. IROs deliver conflict-free decisions that help clinical and claims management professionals better allocate healthcare resources.
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. Medical Necessity: Typically, Cigna considers medical, surgical, diagnostic, psychiatric, substance abuse or other health care technologies, supplies, treatments, procedures, or devices to be medically necessary if the following criteria are met:
 - Required to diagnose or treat an illness, injury, disease or its symptoms;
 - In accordance with generally accepted standards of medical practice;
 - Clinically appropriate in terms of type, frequency, extent, site and duration;
 - Not primarily for the convenience of the patient, physician or other health professional.
 - Not more costly than an alternative service(s), medication(s) or supply(ies) that is at least as likely to produce equivalent therapeutic or diagnostic results with the same safety profile as to the prevention, evaluation, diagnosis or treatment of the member's sickness, injury, condition, disease or its symptoms; and
 - Rendered in the least intensive setting that is appropriate for the delivery of the services, supplies or medications. Where applicable, the Medical Director or Review Organization may compare the cost-effectiveness of alternative services, supplies, medications, or settings when determining least intensive setting.

1 Connect Bronze 6500 Indiv Med Deductible Plan Booklet pg. 26 of 112

2 Connect Bronze 6500 Indiv Med Deductible Plan Booklet pg. 72 of 112

8. 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).
9. 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 ICD or state guidelines).
10. Non-Urgent: A situation that is considered routine in nature.
11. 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.
12. 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
13. 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
14. 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
15. Retrospective Review: A review performed when care or service has already been completed, or a discharge has occurred prior to an authorization of a coverage request.
16. Urgent: Any request for medical care or treatment where a delay in making non-urgent care determination:
 - Could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, based on prudent layperson's judgement, or
 - Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
 - In the opinion of a practitioner with knowledge of the enrollee's medical condition, would subject the enrollee to severe pain that cannot be adequately managed without the care

or treatment that is the subject of the request.

Supporting Documents:

Document/Policy Name	Description
Connect Bronze 6500 Indiv Med Deductible Plan Booklet	Plan specific document that outlines the details of a health insurance plan, including plan and benefit information, claim review procedures, and participation rights. The plan booklet provides comprehensive information about what the plan covers, how it is administered, and the procedures for reviewing claims. It is intended to help members understand their rights and responsibilities under the plan.
CPU 05: Medical Technology Assessment and Coverage Process for EIU Services Including Exceptions and Clinical Trials Policy	The purpose of this policy is to clarify how Cigna reviews requests for medical technologies and develops its medical coverage policies for those technologies determined to be experimental, investigational and unproven(EIU), and for services that are requested through clinical trials.
CPU 07 Healthcare Therapeutic Assessment Committee Process for Determination of Experimental, Investigational, Unproven, Including Off-Label Drug Use.	The purpose of this policy is to clarify how Cigna develops its drugs coverage policies and clinical criteria for those drugs determined to be experimental, investigational and unproven (EIU), and for services that are requested through clinical trials.
Clinical Information to Establish Medical Necessity Guideline (EviCore)	This co-branded Cigna and EviCore Coverage Policy outlines information required to establish medical necessity
Complementary and Alternative Medicine (cigna.com)	This Coverage Policy addresses complementary and alternative medicine diagnostic testing methods, systems, therapies, and treatments that are proposed to reduce disease-based clinical symptoms and improve health and wellness
Clinical Trials (cigna.com)	This policy describes coverage for routine patient care costs/services that are part of an approved clinical trial for a qualified individual under a standard benefit plan administered by Cigna.

EviCore and ASH are separate entities who function as delegates for Cigna and as such maintain their own organizational definitions of EIU. 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.

M/S, MH/SUD and American Specialty Health (ASH) EIU Definitions

Cigna M/S, MH/SUD and ASH
Experimental, investigational or unproven services (EIU) For Cigna plans, the terms experimental, investigational and unproven are used together or interchangeably and this phrase reflects a common intent. Cigna considers medical, surgical, diagnostic, behavioral health or other health care technologies, supplies, treatments, procedures, or devices to be EIU if either of the following criteria is met: • The technology, supply, treatment, procedure, or device has not been demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing any condition or sickness, regardless of U.S. Food and Drug Administration (FDA) approval status; or • when subject to FDA or other appropriate regulatory agency review, is not approved to be lawfully

marketed for any indication.

EviCore EIU Definition

EviCore

Experimental, Investigational, or Unproven Certain studies, treatments, procedures, or devices may be considered experimental, investigational, or unproven for any condition, illness, disease, injury being treated if one of the following is present:

- if there is a paucity of supporting evidence;
- if the evidence has not matured to exhibit improved health parameters;
- if clinical utility has not been demonstrated in any condition; OR
- the study, treatment, procedure, or device lacks a collective opinion of support.

Supporting evidence includes standards that are based on credible scientific evidence published in peer-reviewed medical literature (such as well conducted randomized clinical trials or cohort studies with a sample size of sufficient statistical power) generally recognized by the relevant medical community. Collective opinion of support includes physician specialty society recommendations and the views of physicians practicing in relevant clinical areas when physician specialty society recommendations are not available.

Cigna Pharmacy EIU Definition

Cigna Pharmacy

For Cigna plans, the terms experimental, investigational, and unproven are used together or interchangeably and this phrase reflects a common intent. Cigna considers M/S and MH/SUD drugs and biologics to be EIU if any of the following criteria are met:

- Inadequate volume of existing peer-reviewed, evidence-based, scientific literature to establish whether a technology, supplies, treatments, procedures, or devices is safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;
- When subject to U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency review, not approved to be lawfully marketed for the proposed use;
- The subject of review or approved by an Institutional Review Board for the proposed use except as provided in a clinical trial, as outlined below
- The subject of an ongoing phase I, II, or III clinical trial, except for routine patient care costs related to qualified clinical trials as provided in the clinical trials section below.
- Clinical Trials-Standard benefit plans administered by Cigna cover routine patient care costs/services related to a clinical trial for a qualified individual consistent with the Patient Protection and Affordable Care Act (PPACA) requirements. The individual must be eligible to participate according to the trial protocol and EITHER of the following conditions must be met:
 - The referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate, or
 - The individual provides medical and scientific information establishing that the individual's participation in the qualified trial would be appropriate AND the trial is 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 that meets ANY of the following criteria:
 - 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

- a) ANY of the following:
 - i. Department of Defense
 - ii. Department of Veterans Affairs
 - iii. Department of Energy
- If BOTH 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.

Benefit Classification

Cigna maps benefit classifications for MH/SUD and M/S benefits consistent with generally recognized independent standards of medical practice. Benefits are mapped to Inpatient, Outpatient, Prescription Drugs and Emergency Care. Cigna further sub classifies the Outpatient benefit classification to Office Visit and Outpatient All Other. New codes are assigned benefit classification through Cigna's code attribute process. Cigna's Proprietary Code Attribute Lead (PCAL) receives the code updates from Cigna's Enterprise Reference Data Management (ERDM) team who obtains the information from CMS - Centers for Medicare & Medicaid Services and the American Medical Association (AMA). Code descriptions are reviewed for classification alignment within PMHS Benefit Classes or Proclaim Type Codes, Cigna's claims processing systems. Based on sort and review of code description, most codes will naturally align to the appropriate benefit classification. The PCAL coordinates with the appropriate clinical Subject Matter Experts (SMEs), including medical, pharmacy, and behavioral health for codes that do not naturally align for further determination.

The EIU NQTL applies to all benefit classifications:

Medical/Surgical	Mental Health/Substance Use Disorder
1) inpatient, in-network; 2) outpatient, in-network; 3) prescription drugs	1) inpatient, in-network; 2) outpatient, in-network; 3) prescription drugs

Services Subject to the NQTL

Below table represent M/S codes that are always considered EIU.

Always EIU M/S Codes

Procedure Code	Code Description	Coverage Policy Number	Coverage Policy Name
62291	Injection procedure for discography, each level; cervical or thoracic	0393	Discography
72285	Discography, cervical or thoracic, radiological supervision and interpretation	0393	Discography
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays

	drug response score; first single drug or drug combination		
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays
96932	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion	0240	Skin Cancer Surveillance Technologies
0011M	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk	0520	Molecular and Proteomic Diagnostic Testing for Hematology and Oncology Indications
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle	0004	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds
0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral	0558	Category III Current Procedural Terminology (CPT®) codes
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intraoperative interrogation, programming, and repositioning, when performed)	0558	Category III Current Procedural Terminology (CPT®) codes
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural road mapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	0558	Category III Current Procedural Terminology (CPT®) codes
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes	0574	Cardiac Omnibus
0439T	Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to code for primary procedure)	0558	Category III Current Procedural Terminology (CPT®) codes
0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (e.g., thoracotomy, transapical)	0501	Transcatheter Heart Valve Procedures

0511T	Removal and reinsertion of sinus tarsi implant	0558	Category III Current Procedural Terminology (CPT®) codes
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	0558	Category III Current Procedural Terminology (CPT®) codes
0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report	0558	Category III Current Procedural Terminology (CPT®) codes
0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure	0558	Category III Current Procedural Terminology (CPT®) codes
0560T	Anatomic model 3D-printed from image data set(s); each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure) (Use 0560T in conjunction with 0559T) (Do not report 0559T, 0560T in conjunction with 76376, 76377)	0558	Category III Current Procedural Terminology (CPT®) codes
0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	0558	Category III Current Procedural Terminology (CPT®) codes
0564T	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays
0565T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation	0552	Stem Cell Therapy for Orthopaedic Applications
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	0552	Stem Cell Therapy for Orthopaedic Applications
0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis	0501	Transcatheter Heart Valve Procedures
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)	0501	Transcatheter Heart Valve Procedures
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance	0558	Category III Current Procedural Terminology (CPT®) codes
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior	0404	Sacral Nerve and Tibial Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation

	tibial nerve		
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters	0404	Sacral Nerve and Tibial Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	0558	Category III Current Procedural Terminology (CPT®) codes
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	0558	Category III Current Procedural Terminology (CPT®) codes
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	0558	Category III Current Procedural Terminology (CPT®) codes
0644T	Transcatheter removal or debulking of intracardiac mass (e.g., vegetations, thrombus) via suction (e.g., vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	0558	Category III Current Procedural Terminology (CPT®) codes
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	0558	Category III Current Procedural Terminology (CPT®) codes
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	0558	Category III Current Procedural Terminology (CPT®) codes

0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (e.g., fluoroscopy), angiography, and radiologic supervision and interpretation	0558	Category III Current Procedural Terminology (CPT®) codes
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	0558	Category III Current Procedural Terminology (CPT®) codes
0689T	Quantitative ultrasound tissue characterization (nonelastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (e.g., organ, gland, tissue, target structure)	0558	Category III Current Procedural Terminology (CPT®) codes
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRC) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure).	0558	Category III Current Procedural Terminology (CPT®) codes
0737T	Xenograft implantation into the articular surface	0515	Miscellaneous Musculoskeletal Procedures
0742T	Absolute quantitation of myocardial blood flow (AQMBF), single-photon emission computed tomography (SPECT), with exercise or pharmacologic stress, and at rest, when performed (List separately in addition to code for primary procedure)	0558	Category III Current Procedural Terminology (CPT®) codes
0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment	0160	Electrical Stimulation Therapy and Devices in a Home Setting
0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately	0558	Category III Current Procedural Terminology (CPT®) codes
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays
0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as	0099	Tests for the Evaluation of Preterm Labor and Premature Rupture of Membranes

	predictive-risk stratification for spontaneous preterm birth		
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays
0525U	Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug	0203	Tumor In Vitro Chemosensitivity and Chemoresistance Assays
A4575	Topical hyperbaric oxygen chamber, disposable	0053	Hyperbaric and Topical Oxygen Therapies;
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastrroduodenoscopy	0577	Esophageal Mucosal Integrity Testing
E0617	External defibrillator with integrated electrocardiogram analysis	0431	Noninvasive Negative Pressure Ventilation
E0849	Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible	CPG265	Home Traction Devices: Cervical and Lumbar
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	0507	Autologous Platelet-Derived Growth Factors (Platelet-Rich Plasma [PRP])
Q4205	Membrane graft or membrane wrap, per square centimeter	0068	Tissue-Engineered Skin Substitutes

Factually, any M/S service could be considered EIU if the service is used for an off-label reason.

There are no MH/SUD codes/services which are considered always EIU. All behavioral codes/services are reviewed for medical necessity including EIU.

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:

Factors Used to Determine That the NQTL Will Apply to MH/SUD Benefits and M/S Benefits. Cigna utilizes the factors outlined below to determine services that are subject to EIU. In making and determination of the EIU 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. Absence of 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 FDA approval or clearance, as appropriate, 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. Absence of Peer Reviewed Evidence/Publication	2. Not 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. Absence of effective 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. HTAC reviews clinical evidence on drug safety, efficacy and information from treatment guidelines from the National P&T Committee process.

There is no specific formulaic way in which Cigna measures the volume of data needed. Study detail is scrutinized using the scientific method of evidence review. In establishing the factors used to determine what services are considered EIU, Cigna considers the following sources and evidentiary standards:

Factor	Evidentiary Standards and Applicable Thresholds	Source(s) for Each Evidentiary Standard
1. Absence of Food and Drug Administration clearance	1. FDA Safety Protocols and regulatory guidance	1. FDA.gov http://www.fda.gov/RegulatoryInformation/Guidances
2. Absence of Peer Reviewed 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 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)
3. Absence of 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	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

	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 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 the 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).	(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 ▫ Department of Veterans Affairs ▫ Department of Energy • if BOTH 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:**

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. We explicitly cite these services in the plan document to be helpful because customers and clients occasionally ask about whether or not they are covered. We have 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.

Cigna does not reimburse for services performed by an unlicensed/non-certified provider unless required by state law. However, the fact that a service is being provided by a licensed/certified provider does not automatically mean the service should be covered. Licensure itself is not a standalone factor used to determine if a service is appropriate. EIU services are excluded on the basis that there is not enough scientific evidence to prove their efficacy. Hence, the services would be reviewed for medical necessity regardless of who is providing the care.

Customers are made aware of E/I/U services through their plan documentation provided to them at benefit enrollment.

To affirm, only the EIU portion of the services would be denied, while medically necessary services could be reimbursed.

M/S and MH/SUD:

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 the 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.

Pharmacy:

Cigna's Healthcare Therapeutic Assessment Committee (HTAC) applies a consistent process in the development of evidence-based Coverage Policies for a wide variety of drugs and biologics. Cigna's Pharmacy & Therapeutics Committee (P&T Committee) is comprised of independent, actively practicing physicians and pharmacists who represent a broad range of specialty practice areas. In order for a drug/biologic to be considered for policy development through the HTAC, there must be a proposed clinical benefit for the intervention, FDA approval, if appropriate, anticipated significant requests for the service and concern about the use of the service being employed in circumstances where it may not be clinically appropriate, including at request of Cigna Health Plan Commercial Value Assessment Committee.

Step 4: Demonstration of comparability and stringency as written.

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

- (1) Documentation of each factor identified and defined in Step 2 that was applied to determine whether the NQTL applies to MH or SUD benefits and medical/surgical benefits in a classification, including, as relevant;
 - (A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the NQTL applies, MH or SUD benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the NQTL would or would not apply; and
 - (B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of

their application;

- (2) In each classification in which the NQTL applied to MH or SUD benefits, comparison of how the NQTL, as written, is designed and applied to MH or SUD benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the NQTL or that address the application of the NQTL;
- (3) Documentation demonstrating how the factors are comparably applied, as written, to MH or SUD benefits and medical/surgical benefits in each classification to determine which benefits are subject to the NQTL; and
- (4) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the NQTL, or the application of the NQTL, to MH or SUD benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including [\[Note that this is asking the issuer to explain/justify any differences between MH/SUD benefits and M/S benefits and to explain why the differences are not more restrictive for MH/SUD benefits\]](#):
 - (A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;
 - (B) In the design of the factors or evidentiary standards; or
 - (C) In the application or design of the NQTL.

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

- (Q2, #5) The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.
 - (Q 2, # 6) If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s) [\[Note that this applies to Step 4 in the context of the processes used to apply the NQTL, such as first-level review, second-level review, and peer-to-peer review\]](#).
- (Q2, #7) If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.

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

- (Q 3, # 1) Production of a large volume of documents without a clear explanation of how and why each document is relevant to the comparative analysis.
- (Q3, # 2) Conclusory or generalized statements, including mere recitations of the

legal standard, without specific supporting evidence and detailed explanations.

- (Q 3, # 3) Identification of processes, strategies, sources, and factors without the required or clear and detailed comparative analysis.
- (Q 3, # 4) Identification of factors, evidentiary standards, and strategies without a clear explanation of how they were defined and applied in practice.

Issuer Response:

As Written:

Cigna's *CPU-05 Healthcare Medical Assessment and Coverage (HMAC) Process for Experimental Investigational and Unproven Services (EIU), Including Exceptions and Clinical Trials* is applied consistently to M/S and MH/SUD services. The internal review of published treatment guidelines that identify covered treatments or services which lack clinical efficacy (defined by the National Institute of Health as "a positive therapeutic effect") also reflect that comparable experts are utilized to make determinations for both for M/S and MH/SUD conditions. These experts evaluate and apply nationally recognized treatment guidelines or other criteria in a comparable manner. Using the factors, sources, and evidentiary standards documented in Step 2, the panel evaluates the service or treatment to determine its appropriateness for approval.

As previously mentioned, the HMAC is comprised of physicians with board certifications including specialties: psychiatry, internal medicine, endocrinology, pediatrics, anesthesiology, family medicine, neurology, colon and rectal surgery, and general surgery. Below table represent M/S codes that are always considered EIU.

The table in step 1 outlines the M/S services that are always considered EIU. As documented in step 1, factually any M/S service could be considered EIU if the service is used for an off-label reason. Also, there are no MH/SUD services which are considered always EIU.

Any behavioral code which could potentially be considered EIU would be used managed through the utilization management process.

Cigna's *CPU-07 Healthcare Therapeutic Assessment Committee Process for Determination of Experimental, Investigational, Unproven, Including Off-Label Drug Use* clarifies how Cigna develops its drug and biologic coverage policies and clinical criteria for those drugs and biologics determined to be experimental, investigational and unproven (EIU), and for services that are requested through clinical trials and is consistently applied to M/S and MH/SUD. Cigna's Healthcare Therapeutic Assessment Committee (HTAC) applies a consistent process in the development of evidence-based Coverage Policies for a wide variety of drugs and biologics. The Healthcare Therapeutic Assessment Committee (HTAC) develops criteria to assist medical directors in determining whether a drug or biologic 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., U.S. Food and Drug Administration), compendia (for example, AHFS Drug Information) and professional society recommendations. HTAC consists of Pharmacists, Medical Directors, and Registered Nurses.

Appeal Rights

If a request is denied as EIU for either M/S or MH/SUD, the customer, his/her authorized representative, or the rendering provider may file an appeal. A Customer can request, orally or in writing, an appeal of any adverse benefit determination, including both initial medical necessity and claim payment-related issues, that the Customer believes is not adequately addressed or

resolved by Customer Service. Appeal forms can be located in the forms center on myCigna.com.

For individual plans, Customers will only be required to complete one level of internal review before pursuing an external review. For individual plan Customers, the internal appeals process will include resolution of disputes regarding initial eligibility decisions for individuals.

The appeals process adheres to state and federal rules. Customers are informed of their appeal rights along with online resources to help guide them through the process. Customers have 180 calendar days from the date of the denial notice to file an appeal. All appeals involve a medical director and are based upon the terms of the benefits plan. Decisions are made within 15 days for preservice and 30 days for post-service unless the request is considered urgent.

The State of Virginia requires specific forms to be submitted, which are the same for MH/SUD as they are for M/S.

Virginia Specific Appointment of Authorized Representative

[PDF] External Review Request Form [PDF]

Physician Certification Expedited External Review Request Form [PDF]

Physician Certification Experimental or Investigational Denials Form [PDF]

Customers who choose to file their own claim may be requested to include documentation supporting the appeal if the denial was based on medical necessity like medical records or statement from the provider describing the service or treatment.

There is a difference in how the MH/SUD appeals process is completed in that Cigna offers an online fillable form option in addition to a print only option, whereas M/S appeals would print the form, complete the form, and submit it.

The same appeals process outlined above also applies to partial denials.

Exclusions:

As previously noted, no MH/SUD services are considered always EIU.

The plan language states "Payment for the following is specifically excluded from this plan: for or in connection with experimental, investigational or unproven services.

Experimental, investigational and unproven services are medical, surgical, diagnostic, psychiatric, substance use disorder or other health care technologies, supplies, treatments, procedures, drug or Biologic therapies or devices that are determined by the utilization review Physician to be:

- not approved by the U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency to be lawfully marketed;
- not demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or Sickness for which its use is proposed;
- the subject of review or approval by an Institutional Review Board for the proposed use except as provided in the "Clinical Trials" sections of this plan; or
- the subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials as provided in the "Clinical Trials" sections of this plan.

In determining whether any such technologies, supplies, treatments, drug or Biologic therapies, or devices are experimental, investigational, and/or unproven, the utilization review Physician 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."

This means that while a service is excluded if EIU, the service will be reviewed by a Cigna physician/peer reviewer to make that determination, and it is not a blanket exclusion

Step 5: Demonstration of comparability and stringency in operation.

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

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

- issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the NQTL complies with Section 146.136(c)(4)(iii)(A);
- (2) Identification of the relevant data collected and evaluated, as required under Section 146.136(c)(4)(iii)(A);
 - (3) Documentation of the outcomes that resulted from the application of the NQTL to MH or SUD benefits and medical/surgical benefits, including:
 - (A) The evaluation of relevant data as required by Section 146.136(c)(4)(iii)(A)];
 - (B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the NQTL contributes to material differences in access to MH or SUD benefits as compared to medical/surgical benefits, in accordance with Section 146.136(c)(4)(iii)(B)(2);
 - (4) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii), including:
 - (A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to MH or SUD benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the NQTL; and To the extent differences in access to MH or SUD benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate MH ad SUD benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply an NQTL, documentation explaining how any such differences are attributable to those standards or measures, as required by Section 146.136(c)(4)(iii)(B)(2)(ii); and
 - (5) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to MH or SUD benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under Section 146.136(c)(4)(iii)(B)(1) to address material differences to comply, in operation with Section 146.136(c)(4), including as applicable:
 - (A) A reasoned explanation of any material differences in access to MH or SUD benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and
 - (B) For a plan or issuer designing and applying one or more NQTLs related to network composition, a discussion of the actions that have been or are being

taken to address material differences in access to in-network MH and SUD benefits as compared to in-network medical/surgical benefits, including those listed in 146.136(c)(4)(iii)(C).

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

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

This FAQ guidance stipulates what plans and issuers should avoid:

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

Issuer Response:

In Operation:

On an annual basis, Cigna reviews applicable operational data with Subject Matter Experts to assess ongoing relevance and makes updates as necessary. Both M/S and MH/SUD EIU reviews follow medical necessity guidelines. Cigna's *CPU-05 Healthcare Medical Assessment and Coverage (HMAC) Process for Experimental Investigational and Unproven Services (EIU), Including Exceptions and Clinical Trials* demonstrates the same factors are used in determining which services are deemed EIU. EIU may be applied when there is no clear Cigna, MCG Clinical Guideline, American Society of Addition Medicine (ASAM) Criteria, or a Cigna Clinical Coverage Policy available.

Where there is no clear guideline, as referenced above, Cigna will assign an inquiry to the coverage policy authors, who are Registered Nurses. The coverage policy authors will conduct an evidence-based review and make recommendations about coverage. The inquiry is performed by reviewing the published peer-reviewed evidence-based literature as well as specialty society guidelines. 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
- nationally recognized professional specialty society recommendations
- FDA-approval/clearance when applicable

During the review process, health disparity issues are taken into consideration and may have an impact on coverage when supported by the evidence. A health disparity is a particular type of health difference that is closely linked with social or economic disadvantages.

Additional variables used to evaluate the 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.

As part of the “in operation” review, Cigna compared the results of UM medical necessity decisions per denial categories. Medical necessity denials are further sub-classified into E/I/U denials.

The data below reflects Virginia IFP 2025 book of business.

Utilization Reviews Requests and Denied:	MH/SUD	MH/SUD Denial Rate	M/S	M/S Denial Rate
<i>In-Network Inpatient:</i>				
Total Number of In-Network Inpatient Prior Authorization Requests	8		296	
Total Number of In-Network Inpatient Prior Authorization Requests Denied	1	13%	44	15%
Total Number of In-Network Inpatient Prior Authorization Requests Denied as EIU	0	0%	0	0%
Total Number of In-Network Inpatient Concurrent Care Reviews Requests	276		2,101	
Total Number of In-Network Inpatient Concurrent Care Denials	9	3%	399	19%
Total Number of In-Network Inpatient Concurrent Requests Denied as EIU	0	0%	0	0%
Total Number of In-Network Inpatient Retrospective Reviews Requests	8		738	

Total Number of In-Network Inpatient Retrospective Review Denials	2	25%	133	18%
Total Number of In-Network Inpatient Retrospective Requests Denied as EIU	0	0%	0	0%
<i>In-Network All Other Outpatient:</i>				
Total Number of In-Network All Other Outpatient Prior Authorization Requests	118		16,507	
Total Number of In-Network All Other Outpatient Prior Authorization Requests Denied	17	14	2,511	15%
Total Number of In-Network All Other Outpatient Prior Authorization Requests Denied as EIU	0	0%	12	0.07%
Total Number of In-Network All Other Outpatient Concurrent Care Reviews Requests	15		2,133	
Total Number of In-Network All Other Outpatient Concurrent Care Denials	4	27%	836	39%
Total Number of In-Network All Other Outpatient Concurrent Authorization Requests Denied as EIU	0	0%	0	0%
Total Number of In-Network All Other Outpatient Retrospective Reviews Requests	3		635	
Total Number of In-Network All Other Outpatient Retrospective Review Denials	0	0%	390	61%
Total Number of In-Network All Other Outpatient Retrospective Requests Denied as EIU	0	0%	0	0%
<i>In-Network Outpatient Office Visit:</i>				
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests	0		671	
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Denied	0	0%	80	12%
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Denied as EIU	0	0%	0	0%
Total Number of In-Network Outpatient Office Visit Concurrent Care Reviews Requests	0		1	
Total Number of In-Network Outpatient Office Visit Concurrent Care Denials	0	0%	0	0%
Total Number of In-Network Outpatient Office Visit Concurrent Authorization Requests Denied as EIU	0	0%	0	0%
Total Number of In-Network Outpatient Office Visit Retrospective Reviews Requests	0		6	
Total Number of In-Network Outpatient Office Visit Retrospective Review Denials	0	0%	0	0%
Total Number of In-Network Outpatient Office Visit Retrospective Requests Denied as EIU	0	0%	0	0%

* 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.

As illustrated by the data above, M/S has a higher volume of EIU denials when compared to MH/SUD (12 compared to 0). When evaluating the total volume of EIU denials in relation to the

total volume of requests, M/S has an EIU denial percentage of 0.05%, and MH/SUD has an EIU denial percentage of 0.00%.

The data below reflects Cigna's 2025 IFP book of business.

Utilization Reviews Requests and Denied:	MH/SUD	MH/SUD Denial Rate	M/S	M/S Denial Rate
<i>In-Network Inpatient:</i>				
Total Number of In-Network Inpatient Prior Authorization Requests	571		2,838	
Total Number of In-Network Inpatient Prior Authorization Requests Denied	4	0.70%	430	15.15%
Total Number of In-Network Inpatient Prior Authorization Requests Denied as EIU	0	0.00%	1	0.04%
Total Number of In-Network Inpatient Concurrent Care Reviews Requests	15,781		24,452	
Total Number of In-Network Inpatient Concurrent Care Denials	782	4.96%	3,515	14.38%
Total Number of In-Network Inpatient Concurrent Requests Denied as EIU	0	0.00%	0	0.00%
Total Number of In-Network Inpatient Retrospective Reviews Requests	56		9,192	
Total Number of In-Network Inpatient Retrospective Review Denials	14	25.00%	1,220	13.27%
Total Number of In-Network Inpatient Retrospective Requests Denied as EIU	0	0.00%	0	0.00%
<i>In-Network All Other Outpatient:</i>				
Total Number of In-Network All Other Outpatient Prior Authorization Requests	560		212,279	
Total Number of In-Network All Other Outpatient Prior Authorization Requests Denied	55	9.82%	31,927	15.04%
Total Number of In-Network All Other Outpatient Prior Authorization Requests Denied as EIU	0	0.00%	208	0.10%
Total Number of In-Network All Other Outpatient Concurrent Care Reviews Requests	695		23,454	
Total Number of In-Network All Other Outpatient Concurrent Care Denials	100	14.39%	9,773	41.67%
Total Number of In-Network All Other Outpatient Concurrent Authorization Requests Denied as EIU	1	0.14%	0	0.00%
Total Number of In-Network All Other Outpatient Retrospective Reviews Requests	10		6,727	
Total Number of In-Network All Other Outpatient Retrospective Review Denials	1	20.00%	3,463	51.48%
Total Number of In-Network All Other Outpatient Retrospective Requests Denied as EIU	0	0.00%	0	0.00%
<i>In-Network Outpatient Office Visit:</i>				
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests	0		0	

Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Denied	0	0.00%	0	0.00%
Total Number of In-Network Outpatient Office Visit Prior Authorization Requests Denied as EIU	0	0.00%	0	0.00%
Total Number of In-Network Outpatient Office Visit Concurrent Care Reviews Requests	2		0	
Total Number of In-Network Outpatient Office Visit Concurrent Care Denials	2	100.00%	0	0.00%
Total Number of In-Network Outpatient Office Visit Concurrent Authorization Requests Denied as EIU	0	0.00%	0	0.00%
Total Number of In-Network Outpatient Office Visit Retrospective Reviews Requests	0		0	
Total Number of In-Network Outpatient Office Visit Retrospective Review Denials	0	0.00%	0	0.00%
Total Number of In-Network Outpatient Office Visit Retrospective Requests Denied as EIU	0	0.00%	0	0.00%

*Routine office visits do not require authorization for M/S or MH/SUD. The reported MH/SUD volume includes requests to review biofeedback. Because biofeedback is a medical service, the requests for coverage under MH/SUD were administratively denied.

As illustrated by the data above, M/S has a much higher volume of EIU denials when compared to MH/SUD (209 compared to 1). When evaluating the total volume of EIU denials in relation to the total volume of requests, M/S has an EIU denial percentage of 0.07% and MH/SUD has an EIU denial percentage of 0.006%.

The above results reflect the fact that Cigna is applying the E/I/U criteria consistently and no more stringently for MH/SUD as compared to M/S; the M/S requests show a higher number of denials for E/I/U.

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:

Conclusion:

In conclusion, the comparative analysis performed for application of the EIU NQTL demonstrates overall compliance with the MHPAEA in-writing and in-operation. Holistically, the number of EIU decisions across the Cigna IFP book of business data reflects lower MH/SUD average denial rates. Cigna's analysis of the benefit plan language and process and policies governing the application of EIU across MH/SUD and M/S benefits and the process by which MH/SUD and M/S services are selected for application of EIU demonstrates comparability and equivalent stringency in-writing and in-operation.

Cigna respectfully submits that the processes, strategies, evidentiary standards, and other factors used to determine MH/SUD services subject to EIU 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 IFP book-of-business data, by members of the legal, compliance, and various business teams, including the following individuals:

Mental Health Parity Legal Team including:

Managing Counsel;
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