### **MHPAEA Summary Form Instructions**

The below summary form is prepared to satisfy the requirements of §15-144 (m)(2), Insurance Article, Annotated Code of Maryland. The summary form must be made available to plan members and to the public on the carrier's website.

Confidential and proprietary information must be removed from the summary form. Confidential and proprietary information that is removed from the summary form must satisfy § 15-144(h)(1), Insurance Article, Annotated Code of Maryland.

The MHPAEA Summary Form includes the MHPAEA Data Report.

Carriers must use the terms defined in COMAR 31.10.51 and the *Instructions for MHPAEA NQTL Analysis Report and Data Report* to complete the summary form.

### **MHPAEA Summary Form**

Under a federal law called the Mental Health Parity and Addiction Equity Act (MHPAEA), [carrier name] must make sure that there is "parity" between mental health and substance use disorder benefits, and medical and surgical benefits. This generally means that financial requirements and treatment limitations applied to mental health or substance use disorder benefits cannot be more restrictive than the financial requirements and treatment limitations applied to medical and surgical benefits. The types of limits covered by parity protections include:

- Financial requirements—such as deductibles, copayments, coinsurance, and out-of-pocket limits; and
- Treatment limitations—such as limits on the number of days or visits covered, or other limits on the scope or duration of treatment (for example, being required to get prior authorization).

Wellfleet has performed an analysis of mental health parity as required by Maryland law and has submitted the required report to the State of Maryland. Below is a summary of that report.

If you have any questions on this summary, please contact Nicole Winchell RN at clinical@wellfleetinsurance.com

If you have questions on your specific health plan, please call (877)657-5030.

#### Overview:

We have identified the five health benefit plans with the highest enrollment for each product we offer in the individual, small, and large group markets, as applicable. These plans contain items called Non-Quantitative Treatment Limitations (NQTLs) that put limits on benefits paid. What these NQTL's are and how the health plans achieve parity are discussed below.

#### 1. Definition of Medical Necessity

NQTL: Medical Necessity Criteria Development – Medical

Classification(s): Inpatient, Outpatient, and Emergency

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Medical Necessity Criteria Development and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Step 1(a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:

Wellfleet delegates its non-Pharmacy Utilization Management to Cigna. Cigna employs the same definition of medical necessity to (M/S) and mental health/substance use disorder (MH/SUD) benefits. Cigna Medical Directors apply the definition of "medical necessity" set forth in the governing plan instrument or the definition required by state law. Notwithstanding the above, Cigna's standard definition of "medical necessity" is as follows:

**Cigna defines "Medically Necessary/Medical Necessity" as follows:** 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 care provider;
- 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.

Note: Cigna Health Management, Inc., an affiliate of CHLIC performs utilization reviews for most medical/surgical (M/S) benefits. A separate entity, eviCore, reviews certain M/S services for Cigna, American Specialty Health, reviews physical therapy and occupational therapy on behalf of CHLIC and both national and regional vendors to perform UM. All entities adhere to Cigna's policies and procedures when performing utilization reviews, and all of the data provided is inclusive of utilization reviews of certain M/S services. Evernorth Behavioral Health ("Evernorth," "EBH" or "Behavioral Health" formerly Cigna Behavioral Health) an affiliate of CHLIC, performs utilization reviews for MH/SUD benefits. No separate entities review MH/SUD services for CHLIC.

\_

<sup>&</sup>lt;sup>1</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

## Step 1 (b): Identify the M/S benefits/services for which Medical Necessity Criteria Development is required:<sup>2</sup>

All M/S and MH/SUD services, whether innetwork or out-of-network must be medically necessary. Services determined by Cigna not to be medically necessary would excluded under the terms of the plan unless otherwise dictated by regulatory requirement or specific plan design.

# Step 1 (b): Identify the MH/SUD benefits/services for which Medical Necessity Criteria Development is required:<sup>3</sup>

All M/S and MH/SUD services, whether in-network or out-of-network must be medically necessary. Services determined by Cigna not to be medically necessary would excluded under the terms of the plan unless otherwise dictated by regulatory requirement or specific plan design.

## Step 2 – Identify the factors used to determine that Medical Necessity Criteria Development will apply to mental health or substance use disorder benefits and medical or surgical benefits<sup>4</sup>

### Medical/Surgical: Cigna

Development of Clinical Criteria
Cigna utilizes its own internally developed
Coverage Policies (medical necessity
criteria) and the MCG<sup>TM</sup> Guidelines when
conducting medical necessity reviews of
M/S services, procedures, devices,
equipment, imaging, diagnostic
interventions and its own internally
developed Coverage Policies and the
MCG<sup>TM</sup> Care Guidelines.
The Medical Technology Assessment

The Medical Technology Assessment Committee (MTAC) establishes and maintains clinical guidelines and medical necessity criteria in the form of published Coverage Policies pertaining to the various medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes. This includes Coverage Policies that address M/S services determined to be experimental and investigational. Determining Medical Necessity Cigna maintains medical necessity criteria (also referred to as clinical criteria) for all medical health services. These criteria are either nationally recognized criteria sets,

### MH/SUD: Cigna

Development of Clinical Criteria
Cigna utilizes its own internally
developed Coverage Policies (medical
necessity criteria) and the MCG<sup>TM</sup>
Guidelines when conducting medical
necessity reviews of MH services,
procedures, devices, equipment,
imaging, diagnostic interventions and
the ASAM criteria for conducting
medical necessity reviews of SUD
services.

The Medical Technology Assessment Committee (MTAC) establishes and maintains clinical guidelines and medical necessity criteria in the form of published Coverage Policies pertaining to the various medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes. This includes Coverage Policies that address MH/SUD services determined to be experimental and investigational. Determining Medical Necessity Cigna maintains medical necessity criteria (also referred to as clinical

<sup>&</sup>lt;sup>2</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>3</sup> *Id*.

<sup>&</sup>lt;sup>4</sup> This section is responsive to Requirement 3 in FAQ Part 45 at 4.

such as those developed by MCG or are developed by Cigna from the comparison of national, scientific and evidenced based criteria sets.

Cigna requires all services theoretically be medically necessary as a condition of coverage; therefore, Medical Necessity applies to all M/S benefits in each benefit classification based on objective clinical criteria unless otherwise dictated by regulatory requirement or specific plan design. This is an industry standard for health insurance coverage. 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.

criteria) for all behavioral health services. These criteria are either nationally recognized criteria sets, such as those developed by MCG, the American Society of Addiction Medicine ("ASAM") or are developed by Cigna from the comparison of national, scientific and evidenced based criteria sets.

Cigna requires all services theoretically be medically necessary as a condition of coverage; therefore, Medical Necessity applies to all MH/SUD benefits in each benefit classification based on objective clinical criteria unless otherwise dictated by regulatory requirement or specific plan design. This is an industry standard for health insurance coverage. 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.

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Medical Necessity Criteria Development to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.<sup>5</sup>

4

<sup>&</sup>lt;sup>5</sup> This section is responsive to Requirements 3 and 4 in FAQ Part 45 at 4.

### Medical/Surgical: Cigna

The use of the various auidelines 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 Cigna's Coverage Policy Unit (CPU), in partnership with Cigna's Medical Technology Assessment Committee ("MTAC"), conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals.

The MTAC's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as set forth below in Cigna's "Levels of Scientific Evidence Table" adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009 and evidenced in Cigna's Medical Technology Assessment and Coverage Process for Determination of Medical Necessity Coverage Criteria Recommendations Policy (OPS-48):

Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.
Level 2: Non-randomized controlled trials (an experimental study, but not an ideal design). Also systematic reviews and meta-analyses of non-randomized controlled trials.
Level 3: Observational studies – e.g. cohort, case-control studies (non-experimental studies). Also

### MH/SUD: Cigna

Same as M/S

systematic reviews and metaanalyses of observational studies. Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also systematic reviews and metaanalyses of retrospective studies. Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.

The MTAC establishes and maintains medical necessity criteria in the form of published Coverage Policies pertaining to the various M/S and MH/SUD health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.6

<sup>&</sup>lt;sup>6</sup> This section is responsive to Requirements 5-7 in FAQ Part 45 at 4.

Step 4(a): Identify and define the processes and strategies used to develop internal Medical Necessity guidelines or modifications to external guidelines that are created by the Plan:

### Cigna

**Development of Criteria – Review and IRR**Clinical coverage policies may incorporate, without limitation and as applicable, criteria relating to U.S. Food and Drug
Administration-approved labeling, the

Administration-approved labeling, the standard medical reference compendia and peer-reviewed, evidence-based scientific literature or quidelines. While Cigna's Coverage Policies and vendor guidelines are reviewed at least once annually, re-review of Coverage Policies and/or topics for new Coverage Policies are identified through multiple channels including requests from the provider community, customers, frontline reviewers, CPU and the impetus of new, emerging and evolving technologies. Also, the company's routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) process is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Of note, the company's most recent MH/SUD IRR exercise did not reveal a need to revise its coverage policies governing reviews of MH/SUD benefits.

### **Medical Necessity Development Processes**

In determining whether health care services, supplies, or medications are Medically Necessary, the HealthPlan Medical Director or Review Organization may rely on the clinical coverage policies maintained by the Health plan 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

Step 4(a): Identify and define the processes and strategies used to develop internal Medical Necessity guidelines or modifications to external guidelines that are created by the Plan: Cigna

Same as M/S – except as follows: **Peer to Peer Variation Analysis** 

With respect to MH/SUD benefits, and in contrast to the process for performing M/S benefit reviews, Cigna ensures that any potential denial of MH/SUD benefits is preceded by a proactive offer to the provider of a peer-to-peer review for certain services including Inpatient and Outpatient All Other benefit classifications. The objectives of proactively seeking a peer-to-peer review is to minimize the risk of issuing a denial where, in fact, the enrollee's clinical situation warrants an approval for medically necessary care yet the provider's request may have incompletely or imprecisely stated the case for medical necessity, or, if a denial is nonetheless issued, mitigating disruption if the loss of coverage results in the enrollee moving to a different treatment type or level of care. This process is beneficial for the enrollee and results in greater approvals and fewer appeals of medical necessity denials.

Cigna's medical necessity review of MH/SUD services is guided by the ASAM Criteria, MCG and Cigna's Clinical Coverage policies and plan documents approved for use in care management determinations. Cigna's Peer-to-Peer review program is triggered when a care manager receives clinical information that does not appear to meet the ASAM Criteria, MCG and Cigna's Clinical Coverage policies and plan documents for initial or prior authorization for level of care requested. In this instance, care managers may offer a lower level of

compendia and peer-reviewed, evidencebased scientific literature or guidelines.

Cigna's Medical Technology Assessment Committee ("MTAC") reviews clinical research and guidelines for new clinical procedures and technologies to determine whether these services have demonstrated clinical efficacy or are still deemed experimental/investigational. Cigna reviews medical and behavioral health national clinical practice guidelines on an annual and bi-annual basis to inform medical necessity criteria and the clinical decision process.

MTAC is composed of physicians and nurses and includes specialists from both medical and behavioral health disciplines. Internal subject matter experts include, but are not limited to orthopedists, neurologists, neurosurgeons, OBGYNs, oncologists, primary care physicians, internist, surgeons, urologists, pulmonologists cardiologists, psychologists and psychiatrists. 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 medical necessity coverage policies, in consultation with Coverage Policy SMEs, as part of the annual clinical review. These recommendations are offered to MTAC for discussion and ultimately require a vote of the majority to be accepted to ao in to effect. 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 SME: These are clinical subject matter experts - representing a range of clinical specialties, including, as relevant, MH/SUD experts (see the "Behavioral Health" clinicians listed in the "Coverage Policy SME" tab – consulted

care to ensure there is no delay or impediment to care where the medical necessity criteria is met. If that level of care is not accepted by the requesting provider (treating practitioner), the case is referred to Peer-to-peer review with a behavioral health physician reviewer.

The Peer-to-Peer review is available for any coverage request for which Cigna anticipates issuing a denial Cigna incorporates into its MH/SUD utilization review process a requirement that prior to issuing a denial - a Cigna clinician proactively solicit a peer-topeer review with the rendering provider. After completing the peer-to-peer review with the rendering provider, the Ciana Medical Director makes a decision to approve or deny the requested service, based on all of the clinical information provided. Peer-topeer reviews that are declined by the requesting provider result in the Ciana Medical Director making a decision to approve or deny the requested service based on the clinical information that was submitted and obtained by the Ciana clinician. All reconsideration and appeal options are available if a case results in a denial, just as they are available for denials issues for an M/S request.

when drafting or reviewing coverage policies).

The MTAC's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as set forth in Cigna's "Levels of Scientific Evidence Table" as stated in Step 3 above. The MTAC establishes and maintains medical necessity criteria in the form of published Coverage Policies pertaining to the various M/S and MH/SUD health services, therapies, procedures, devices, technologies and pharmaceuticals to be used for utilization management purposes.

### **Medical Necessity Appeals**

1. Internal Appeals: Cigna follows the same a single-level internal appeal process for resolving disputes regarding pre/post-service benefit coverage and medical necessity denials of requested benefits for both M/S and MH/SUD. For medical necessity reviews a second health care professional, who was not involved in any previous decision and is not a subordinate of the individual in the previous decision, performs a single level appeal, whether expedited or standard.

Expedited appeals are completed within 72 hours. Standard level 1 and level 2 preservice medical necessity appeals are completed within 15 calendar days and standard post-service level 1 and level 2 medical necessity appeals are completed within 30 calendar days, post-service administrative appeals are completed within 30 calendar days. The assigned appeal processor notes the adverse determination as a denial in our system and communicates the determination by phone to the requesting party if the appeal was handled as expedited. At each step in the process, Cigna provides written notification of the outcome and resolution, including the clinical rationale for the determination to the member and the treating provider or facility.

2. External Appeals: Ciana informs customers of their right to request an external appeal to an IRO, at no cost to the Customer, in the final internal appeal denial letter for both M/S and MH/SUD external appeals. 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 the provision of program information and IRO program description. All records and materials relevant to the adverse determination and included in the previous appeal files are presented for review to an Independent Review Organization (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. Standard external appeals are completed within 45 days and expedited external appeals are completed within 72 hours.

### Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the efficacy and validity of Medical Necessity guidelines Wellfleet

The number of utilization review decisions across the Wellfleet - Cigna book of business data noted below, reflects significantly less denial rates on average across all benefit classifications for utilization management for MHSUD including prior authorization, concurrent review and retrospective review for medical necessity denials. MedSurg services denials are significantly higher than medical necessity denials of MH/SUD services.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the efficacy and validity of Medical Necessity guidelines Wellfleet

Same as M/S

### Cigna

Cigna regularly reviews utilization management data to evaluate and ensure operational compliance of the medical management suite of NQTLs, including Medical Necessity and Appeals, Prior Authorization and Concurrent Review. Data is reviewed by benefit classification and sub-classification to calculate denial rates to ensure comparability. Ciana's application of the medical necessity NQTL, specifically approvals and denials rates, for Prior Authorization, Retrospective Review, and Concurrent Review across benefit classifications for Wellfleet-Cigna plans revealed no statistically significant discrepancies in medical necessity denial rates as-between MH/SUD and M/S benefits. Cigna utilizes appeals data to review the number of utilization review decisions across the book-of-business. Appeals data is delineated by pre and post services and includes prior authorization and concurrent review, overturned for the same time period relating to the utilization management data metrics. Data reflected for Wellfleet book of business from Ciana shows overall comparable overturn rates across benefit classifications.

### Cigna

Same as M/S

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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<sup>7</sup>

### As written:

### Cigna

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 classification. 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. Compliance is further demonstrated through Cigna's uniform definition of Medical Necessity for M/S and MH/SUD benefits.

<sup>&</sup>lt;sup>7</sup> This section is responsive to Requirement 8 in FAQ Part 45 at 4.

Consistency in policy development, process and application evidences compliance with the NQTL requirement that the medical management process be applied comparably, and no more stringently, to MH/SUD services than to M/S services. The only difference between the assessment of medical necessity for MH/SUD and M/S services is Ciana's peer-to-peer process described in Step 4. While this process is different for MH/SUD it is nonetheless more favorable for MH/SUD services. If Cigna's pro-active, volunteer Peer-to-Peer review were not applicable to MH/SUD services, and such services followed a similar process to the M/S benefit, services that were approved due to such Peer-to-Peer review, would have been much more likely to have resulted in a denial without additional information or discussion to meet clinical criteria. The provider has the right to decline the peer review and move forward retaining the same rights post-decision/denial. Cigna's pro-active Peer-to-Peer review is more favorable to the enrollee and the rendering/requesting provide resulting in a less stringent, more advantageous process for MH/SUD claims because it is proactive, as compared to the process for M/S claims whereby any peer-to-peer review is, unless otherwise required by state law, conducted reactively, i.e., if the rendering provider outreaches to Ciana.

Cigna has not identified any additional discrepancies in operational policies between MH/SUD and M/S benefits where the discrepancies present a comparability or stringency problem within the context of the NQTL requirement. Instances where discrepancies between the process of administering MH/SUD and M/S benefits do not present an NQTL issue include, for example, situations where a discrepancy in process is more advantageous to the administration of MH/SUD benefits than M/S benefits such as the pro-active behavioral health peer-to-peer review process outlined herein.

### In operation:

### <u>Cigna</u>

services.

Approximately 37% of all pre-service MH/SUD peer-to-peer reviews inclusive of read only reviews, which includes a Medical Director review of the medical file without discussion when a peer-to-peer is scheduled but the requesting provider does not attend, in Cigna's book-of-business data resulted in approvals that may otherwise have resulted in a medical necessity denial.

Additionally, Cigna conducts routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) testing is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Corrective action is initiated if a score falls below 85% and if the results are below 90% the Medical Director will evaluate the scores and decide whether to convene a review process with the Medical Directors/Physician Reviewers. Of note, the company's most recent MH/SUD IRR exercise did not reveal a need to revise its coverage policies governing reviews of MH/SUD benefits. Wellfleet

The number of utilization review decisions across the Wellfleet - Cigna book of business data noted below, reflects significantly less denial rates on average across all benefit classifications for utilization management for MHSUD including prior authorization, concurrent review and retrospective review for medical necessity denials. MedSurg services denials are significantly higher than medical necessity denials of MH/SUD

<u>Findings and Conclusions:</u> Wellfleet has determined that Medical Necessity Criteria Development is applied for MH/SUD benefits in a manner that is comparable to and

no more stringent than that of M/S services, both as written and in operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose Medical Necessity Criteria Development.

### **NQTL: Medical Necessity Criteria Development**

### Classification(s): Prescription Drugs

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Medical Necessity Criteria Development and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Step 1 (a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:8

"Medical Necessity Criteria" is defined as guidelines utilized that ensure the clinical appropriateness of a prescription drug. Medical Necessity Criteria applies to M/S and MH/SUD prescription drugs that require prior authorization. Wellfleet imposes prior authorization requirements on certain M/S and MH/SUD drugs to ensure that members receive clinically appropriate and medically necessary medications.

Medically Necessary/Medical Necessity: Medically Necessary or Medical Necessity means health care services that a Physician, exercising prudent clinical judgment, would provide for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice;
- 2. Clinically appropriate, in terms of type, frequency, extent, site and duration and considered effective for an illness, injury or disease; and
- 3. Not primarily for the convenience of an Insured Person, 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 an Insured Person's illness, injury or disease.

The fact that any particular Physician may prescribe, order, recommend or approve a service or supply does not, of itself, make the service or supply Medically Necessary.

<sup>&</sup>lt;sup>8</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

In the Wellfleet Formulary Management Policy, it states "Medical Necessity Criteria: Guidelines utilized that ensure the clinical appropriateness of a prescription drug. Also referred to as 'UM Guidelines'."

### Step 1 (b): Identify the M/S benefits/services for which Medical Necessity Criteria Development is required:9

All benefits and services requiring Prior Authorization

Step 1(b): Identify the MH/SUD benefits/services for which Medical Necessity Criteria Development is required:10

All benefits and services requiring Prior Authorization

Step 2 – Identify the factors used to determine that Medical Necessity Criteria Development will apply to mental health or substance use disorder benefits and medical or surgical benefits<sup>11</sup>

### Medical/Surgical:

Wellfleet applies the following factors to determine whether to develop or adopt a medical necessity policy:

- Lack of adherence to quality standards
- High variability in cost within drugs in a given therapeutic class
- Anticipated excessive utilization Wellfleet uses the following sources of guidelines for its medical necessity criteria:
  - FDA Prescribing Information
  - Professionally recognized treatment guidelines
  - Nationally recognized Compendia

     such as Truven Health Analytics
     Micromedex DrugDEX
  - Peer Reviewed medical literature

#### MH/SUD:

Wellfleet applies the following factors to determine whether to develop or adopt a medical necessity policy:

Same as M/S

Wellfleet uses the following sources of guidelines for its medical necessity criteria:

- FDA Prescribing Information
- Professionally recognized treatment guidelines, such as ASAM or APA criteria
- Nationally recognized Compendia

   such as Truven Health Analytics
   Micromedex DrugDEX
- Peer Reviewed medical literature

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source

 $<sup>^{\</sup>rm 9}$  This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>10</sup> Id.

<sup>&</sup>lt;sup>11</sup> This section is responsive to Requirement 3 in FAQ Part 45 at 4.

or evidence relied upon to design and apply Medical Necessity Criteria Development to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.<sup>12</sup>

### Medical/Surgical:

### Α.

- Factor 1: lack of adherence to quality standards – This factor carries more weight due to the safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  - o Source: FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care, nationally recognized Compendia Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.
  - Evidentiary Standard: P&T Committee members discuss safety of newly released products to determine if they have potential for unsafe use.
     Sources listed above are compiled by Wellfleet's Clinical Pharmacist into New Drug Reviews and Therapeutic Class Reviews.
     These reviews contain information on indications, dosing & administration, clinical and comparative

### MH/SUD:

Α.

- Factor 1: lack of adherence to quality standards – This factor carries more weight due to the safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  - o Sources: FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as ASAM criteria or APA treatment guidelines, nationally recognized Compendia Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.
  - Evidentiary Standard: Same as M/S

<sup>&</sup>lt;sup>12</sup> This section is responsive to Requirements 3 and 4 in FAQ Part 45 at 4.

efficacy, clinical guidelines, contraindications & special populations, etc. These are forwarded to the P&T committee prior to the meetings for their review. Meeting discussions include an analysis of: appropriate dosing, potential overdose, prescribing by particular specialty provider, adherence or potential non-adherence to guidelines, etc.

- Factor 2: high variability in cost within drugs in a given therapeutic class
  - Source: First Databank
    (FDB), internal market and
    competitive analysis,
    therapeutic class total net
    cost analysis
  - Evidentiary Standard: High cost is defined as \$670/month supply. Also taken into account are the availability of alternate therapies (brand/generic) & lowest total net cost for course of therapy for given conditions.
- Factor 3: anticipated excessive utilization
  - o Source: Aggregated data or non-identifiable utilization reports, FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as nationally recognized Compendia Truven Health Analytics Micromedex DrugDEX (DrugDEX), and

- Factor 2: high variability in cost within drugs in a given therapeutic class
  - Sources: Same as M/S
  - Evidentiary Standard: Same as M/S

- Factor 3: anticipated excessive utilization
  - Source: Aggregated data or non-identifiable utilization reports, FDA Prescribing Information, professionally recognized treatment auidelines used to define clinically appropriate standards of care such as ASAM criteria or APA treatment guidelines, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.

- peer-reviewed medical literature.
- Evidentiary Standard: Clinical Pharmacist reviews claims data every 6 months and compares actual utilization against the recommendations in the sources identified above (e.g. FDA prescribing information, dosing schedules, etc.) to determine whether a drug is being used excessively or inappropriately. "Excessive utilization" is defined as anything above the FDA approved dosing schedule or recommended dosage in peer-reviewed medical iournals. If the Clinical Pharmacist determines a drug is subject to potential excessive utilization, the Clinical Pharmacist or the P&T Committee may recommend applying prior authorization to the Value Assessment Committee (VAC). The VAC reviews the Clinical Pharmacist's and the P&T Committee recommendation to approve the decision of applying prior authorization.
- Evidentiary Standard: Same as M/S

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.<sup>13</sup>

Step 4(a): Identify and define the processes and strategies used to develop internal Medical Necessity guidelines or modifications to external guidelines that are created by the Plan:

Medical Necessity considerations are built into drug specific Prior authorization criteria for prescription drugs and are analyzed semi-annually for parity. The same Off-Label policy and non-formulary drug exception policy, which are reviewed annually by the Pharmacy & Therapeutics Committee, are used for both MH/SUD and M/S drugs. These policies can be found at https://wellfleetrx.com/students/formulari es/. The same P&T committee, comprised of a range of specialists, make decisions on appropriateness of medical necessity criteria based on the factors, sources, and evidentiary standards stated above.

Key steps in the process for developing standards:

- After determination is made by the P&T Committee and Value Assessment Committee to assign Prior Authorization to a particular drug product (see Prior Authorization NQTL response for factors/sources), the medical necessity criteria to accompany this designation must be made.
- When a new drug product or new indication is approved by the FDA,

Step 4(a): Identify and define the processes and strategies used to develop internal Medical Necessity guidelines or modifications to external guidelines that are created by the Plan:

Medical Necessity considerations are built into drug specific Prior authorization criteria for prescription drugs and are analyzed semi-annually for parity. The same Off-Label policy and non-formulary drug exception policy, which are reviewed annually by the Pharmacy & Therapeutics Committee, are used for both MH/SUD and M/S drugs. These policies can be found at https://wellfleetrx.com/students/formulari es/. The same P&T committee, comprised of a range of specialists, make decisions on appropriateness of medical necessity criteria based on the factors, sources, and evidentiary standards stated above.

Key steps in the process for developing standards:

Same as M/S

<sup>&</sup>lt;sup>13</sup> This section is responsive to Requirements 5-7 in FAQ Part 45 at 4.

a clinical pharmacist is assigned to review the drug. A clinical pharmacist will be assigned as the author to complete the new drug review is responsible for creating a PA policy base criterion. The author will create a draft policy, which will be discussed at the next P&T Committee meeting for review, feedback, and approval. The author will revise the PA policy, if necessary, based on input from specialists. This criterion will be based off of the FDA-approved indication, dosage, and administration information in the package insert, as well as pertinent demographic information from the pivotal study leading to the approval of the drug product.

- In the period of time between designation and finalization of the specific criteria, the guideline entitled "Guidelines for Drugs Without PA Criteria" is used for approval/denial of prior authorization requests. This guideline requires the drug to be FDA approved for the indication the provider is attempting to use it for, and that the patient meets any standards within the "Indications and Usage" section of the FDA label (age, gender, genetic phenotype, etc.)
- In most cases, a drug-specific base criteria to potentially use in the future is presented during the P&T Committee New Drug Review and discussed. There are a few exceptions to the utilization of a drug specific criteria. For example, medication class guidelines may group many medications under one large umbrella (ex. Fertility Drugs). The creation of these

- guidelines follows the same procedure listed here.
- Wellfleet's Clinical Pharmacist utilizes base criteria and updates based on any new information released since the drug was last discussed at P&T. If a base criteria is not available, the medical necessity criteria shall be based on FDA labeling information, relevant clinical treatment guidelines, peerreviewed medical literature, and national compendia.
  - Wellfleet's Clinical Pharmacist utilizes the sources listed above in the creation of this criteria.
- After finalization of the drugspecific medical necessity criteria, it is presented to the P&T Committee for final approval prior to use.

Composition of the committee used to develop internal standards:

- Medical Necessity criteria is created by Wellfleet's Clinical Pharmacist (PharmD., RPh)
- Approval of criteria is done by Wellfleet's P&T Committee, composed of healthcare providers from varying specialties that covers a wide range of diagnoses and care settings. These providers must be in good standing with their licensing boards and have at least 5 years of experience in their current field. Examples of specialties represented on this committee: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Pediatrics, Specialty Pharmacy, Psychiatry.

Composition of the committee used to develop internal standards:

Same as M/S

The selection and use of external or independent experts:

• Same as M/S

The selection and use of external or independent experts:

 The P&T committee is composed of at least 80% external members that have no affiliation or employment with Wellfleet. These members are expected to disclose any Conflict of Interest, bias, etc. They are required to sign a Conflict of Interest statement annually.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the efficacy and validity of Medical Necessity guidelines

### **Policy Review Analysis:**

In review of the MH/SUD in comparison to M/S written policies to determine medical necessity, a sample set of 6 policies from each classification were reviewed. Both sets of PA criteria included the following: FDA indication, age restrictions, and alignment with package insert. The MH/SUD policies included language to ensure a patient was monitored within a setting for safety (example: REMS program). Some of the policies required the medication to be prescribed by or in consultation with a particular physician specialty. One instance, a policy did require a trial of two medications from different classes before the requested drug could be used. This language was in alignment with the inclusion criteria used from the clinical trial that was used for FDA approval. The M/S policies required certain clinical parameters to be met for Prior Authorization. Examples include: hepatitis C viral load, blood eosinophil level, lesion volume/count for multiple sclerosis, confirmation of gene mutation), included trial and failure language of 1 to 2 agents prior to the use of the requested

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the efficacy and validity of Medical Necessity guidelines

**Policy Review Analysis:** 

Same as M/S

agent, included a list of reasons why the medication would not be approved, and listed renewal criteria required for each subsequent approval. Some of the policies required the medication to be prescribed by or in consultation with a particular physician specialty. Sources used to develop PA criteria for both MH/SUD and M/S policies included FDA approved prescriber Information, nationally recognized compendia, and established clinical guidelines. This analysis finds the two sets of criteria (MH/SUD and M/S) to be similar in clinical requirements for medical necessity. All policies were reviewed and approved by the same P&T Committee.

### **Ongoing Monitoring Activities:**

All policies are reviewed and updated based on clinical guideline, FDA labeling, safety, etc updates at least annually. A quarter of all medical necessity criteria are reviewed each quarter, with updates brought to the P&T Committee for approval. Selection of the criteria to be updated each quarter is based strictly on last update date to ensure an even selection of updates and that each guideline is reviewed at an appropriate time.

**IRR scores:** Interrater reliability results for reviews performed in 2022 were 93.94% for M/S reviews.

### **Ongoing Monitoring Activities:**

Same as M/S

**IRR scores**: Interrater reliability results for reviews performed in 2022 were 90.53% for MH/SUD reviews.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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<sup>14</sup>

As written: As stated in Step 1, for both MH/SUD and M/S services, all benefits and services requiring Prior Authorization are subject to medical necessity criteria development. As demonstrated in Steps 2 and 3, the factors used to determine whether to develop or adopt a medical necessity policy are identical for MH/SUD and M/S services. The evidentiary standards are also the same, though the sources differ slightly for MH/SUD services, as ASAM criteria or APA treatment guidelines are reviewed to determine whether a particular factor's evidentiary standards has been met. Although these sources are only consulted for MH/SUD services, this difference is nonetheless parity compliant because these sources are nationally recognized industry standard clinical resources specifically targeted for MH/SUD conditions. Thus, the benefits subject to medical necessity criteria and the factors, sources, and evidentiary standards used to determine medical necessity criteria development for MH/SUD and M/S services are comparable.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Medical Necessity Criteria Development to MH/SUD drugs, <u>as written</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Medical Necessity Criteria Development to M/S drugs.

In operation: Wellfleet conducted a medical necessity policy review analysis as further detailed in Step 4 and found the sets of criteria for MH/SUD and M/S drugs to have comparable clinical requirements for medical necessity. All policies are reviewed and updated based on clinical guideline, FDA labeling, safety, etc updates at least annually. A quarter of all medical necessity criteria are reviewed each quarter, with updates brought to the P&T Committee for approval. In addition, IRR scores were comparable for both MH/SUD and M/S drugs and were above 90%. Thus we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Medical Necessity Criteria Development to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Medical Necessity Criteria Development to M/S drugs.

**Findings conclusions**: Both as written and in operation the processes, strategies, evidentiary standards, and other factors used to apply Medical Necessity Criteria Development to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Medical Necessity Criteria Development to M/S benefits in the prescription drug classification. Therefore, the plan finds that the comparative

<sup>&</sup>lt;sup>14</sup> This section is responsive to Requirement 8 in FAQ Part 45 at 4.

analysis demonstrates its Medical Necessity Criteria Development practices are compliant with MHPAEA.

### 2. Prior Authorization Review Process

#### NQTL: Prior Authorization – Medical

Classification(s): Inpatient In-Network, Inpatient Out-Of-Network

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Prior Authorization and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Step 1(a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:15

Prior Authorization (Preauthorization or "PA") is a decision prior to a member's receipt of a Covered Service, procedure, or device that the Covered Service, procedure or device is Medically Necessary.

Wellfleet delegates its non-Pharmacy Utilization Management to Cigna . Cigna is responsible for determining which non-Pharmacy benefits are eligible for PA. As such, Cigna's utilization management policies are used to determine prior authorization factors, sources, and evidentiary standards. Once the benefits subject to prior authorization are determined, Cigna performs utilization management on Wellfleet's behalf. Their policies are used to determine operational aspects of Prior Authorization.

Step 1 (b): Identify the M/S benefits/services for which Prior Authorization is required: 16

Please see attached which details benefits subject to PA:

Step 1(b): Identify the MH/SUD benefits/services for which Prior Authorization is required:17

Please see attached, which details benefits subject to PA:

24

<sup>&</sup>lt;sup>15</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>16</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>17</sup> Id.

### Step 2 – Identify the factors used to determine that Prior Authorization will apply to mental health or substance use disorder benefits and medical or surgical benefits <sup>18</sup>

### Medical/Surgical:

### A. Factors for determining whether to apply PA:

Wellfleet delegates Utilization
Management, including Prior
Authorization, to Cigna. As such, Wellfleet
utilizes Cigna's factors for determining
when to apply PA. When determining
that M/S benefits are subject to Prior
Authorization, Cigna conducts a costbenefit analysis based upon the following
factor:

Services covered under a Cignaadministered benefit plan, including M/S benefits, may require Prior Authorization to achieve a variety of objectives, including the verification of the appropriate utilization of services by type/level of care and place/setting of service under benefit plans administered by Cigna (clinical appropriateness) the value of the service exceeds the administrative costs, and verification that a service will be rendered for a covered benefit.

All Inpatient admissions are subject to prior authorization review, without service/procedure level distinctions for the inpatient benefit classification based upon high cost, high risk and complexity for members receiving the service.

### B. Factors for determining whether to remove PA:

Once Wellfleet receives the list of services subject to PA from Cigna, Wellfleet can choose to remove PA from certain

### MH/SUD:

### A. Factors for determining whether to apply PA:

Same as M/S.

### B. Factors for determining whether to remove PA:

Same as M/S.

<sup>&</sup>lt;sup>18</sup> This section is responsive to Requirement 3 in FAQ Part 45 at 4.

benefits/ services. Wellfleet uses the following factors to determine whether to remove PA from certain services:

- 1. ROI
- 2. School preference/ selection (used only to remove PA)

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Prior Authorization to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.<sup>19</sup>

### Medical/Surgical:

### A. Factors for determining whether to apply PA:

1. Cost Benefit Analysis conducted by Cigna

#### Sources

- COGNOS Internal claims database including measures for volume of services approved, denied, total authorizations, denial rates estimated average cost, cost to review, estimated savings, per member per month savings, return on investment and contracted rates.
- Expert Medical Review
- Input from national vendors
- Medical Economics biannual provider and facility analyses report for codes not included on precertification list

#### MH/SUD:

### A. Factors for determining whether to apply PA:

Same as M/S

### Sources:

Same as M/S

<sup>&</sup>lt;sup>19</sup> This section is responsive to Requirements 3 and 4 in FAQ Part 45 at 4.

- Nationally recognized evidencebased guidelines and CMS and HCPS updates
- Industry accepted procedures codes developed by:
- American Medical Association (AMA) publication of the Current Procedural Terminology (CPT) book
- American Hospital Association (AHA) publication of revenue codes
- American Formulary Association (AFA) publication of codes
- Centers for Medicare and Medicaid Services (CMS) publication of codes

### **Evidentiary Standards**

### <u>Inpatient</u>

The evidentiary standard relied on to determine whether to apply prior authorization to inpatient M/S benefits is whether application of prior authorization produces positive financial savings, as measured in the aggregate across the Cigna-administered book-of-business. Cigna has determined the value of subjecting all inpatient In-Network and Out-of-Network M/S services to prior authorization/precertification review must exceed the administrative costs by at least 1:1. The ROI ratio is calculated using the following formula:

- The actual or anticipated denial rate of the service multiplied by the average unit cost (or, as applicable, cumulative cost) of the service, with the resulting figure divided by the estimated cost to review the total number of services.
- For services for which Cigna maintains historic claims data, Cigna calculates the denial rate by reference to the actual denial

### **Evidentiary Standards**

### <u>Inpatient</u>

The evidentiary standard relied on to determine whether to apply authorization to inpatient MH/SUD benefits whether application of prior authorization produces positive financial savings, as measured in the aggregate across the Cigna-administered book-ofbusiness. Cigna has determined the value of subjecting all inpatient In-Network and Out-of-Network MH/SUD services to prior authorization/precertification review must exceed the administrative costs by at least 1:1. The ROI ratio is calculated using the following formula:

- The actual or anticipated denial rate of the service multiplied by the average unit cost (or, as applicable, cumulative cost) of the service, with the resulting figure divided by the estimated cost to review the total number of services.
- For services for which Cigna maintains historic claims data, Cigna calculates the denial rate by reference to the actual denial

rate as reflected in the historic book-of-business claims data it maintains. The average unit cost of the service is calculated based on Cigna's historical paid claims for the service across its commercial book of business. The estimated cost to perform a coverage review is \$40 per review, which is informed by costs/expenses such as personnel salaries and time.

Clinical Appropriateness is defined as those services that as determined in the exercise of the professional judgement of Cigna's internal medical experts, are in accordance with generally accepted standards of care and nationally recognized guidelines. Nationally recognized guidelines are included in Cigna's "Levels of Scientific Evidence Table" adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009 as outlined in the development of clinical criteria of Medical Necessity.

rate as reflected in the historic book-of-business claims data it maintains. The average unit cost of the service is calculated based on Cigna's historical paid claims for the service across its commercial book of business. The estimated cost to perform a coverage review is \$100 per review, which is informed by costs/expenses such as personnel salaries and time.

Clinical Appropriateness is defined as those services that as determined in the exercise of the professional judgement of Cigna's internal medical experts, are in accordance with generally accepted standards of care and nationally recognized guidelines. Nationally recognized guidelines are included in Cigna's "Levels of Scientific Evidence Table" adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009 as outlined in the development of clinical criteria of Medical Necessity.

The ROI ratio is calculated using the following formula:

 The actual or anticipated denial rate of the service multiplied by the average unit cost (or, as applicable, cumulative cost) of the service, with the resulting figure divided by the estimated cost to review the total number of services.

For services for which Cigna maintains historic claims data, Cigna calculates the denial rate by reference to the actual denial rate as reflected in the historic book-of-business claims data it maintains. The average unit cost of the service is calculated based on Cigna's historical paid claims for the service across its commercial book of business. The

### B. Factors for determining whether to remove PA:

- Factor 1: Return on investment Source: Wellfleet claims data, Charges by delegated Review Organization to perform Prior Authorization on add-on services
- Evidentiary Standard: ROI<1 is required to remove a benefit from the PA list. ROI of a specific service type is calculated as follows: Wellfleet (through its Chief Medical Officer and Finance Department) determines the annual savinas from prior authorization by adding up all approved charges for a specific service type using the initial ICD-10 code (to identify M/S vs. MH/SUD) and & specified CPT codes (to identify a specific service type) that were requested but denied and not overturned on appeal
- Then, Wellfleet determines the annual cost of prior authorization for a specified service type as follows:
- For each month of the year, Wellfleet multiplies Cigna's per member per month charge for prior authorization of the specified service type, times the number of members in all the plans delegated to Cigna for utilization review that month.
- Wellfleet adds the costs above for all twelve (12) months together to yield the total annual cost of prior authorization of that specified service type

estimated cost to perform a coverage review is \$100 per review, which is informed by costs/expenses such as personnel salaries and time.

### B. Factors for determining whether to remove PA:

Same as M/S

- Wellfleet determines the ROI of a specified service type by dividing the total annual savings by the total annual costs for that specified service type.
- If ROI is < 1, prior authorization will be removed from the service
- Factor 2: School (client)
   preference [Note: this factor is only
   used to remove Prior Authorization
   from MH/SUD benefits, and is never
   used to apply PA to MH/SUD
   benefits, thus this factor only serves
   to make MH/SUD benefits more
   accessible to members by
   potentially eliminating PA from
   certain MH/SUD services].
- Source: School (client) decision to remove a benefit from the list\*
- Evidentiary Standard: PA will be removed if the school (client) states that they do not want a certain benefit to be subject to PA and:
  - (a) that preference is negotiated as part of the sales process, or
  - (b) that preference is provided in writing in an independent decision by the school (client) at a later date.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).

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.<sup>20</sup>

## Step 4(a): Briefly describe the processes by which Prior Authorization is applied to M/S benefits:

A. Timelines and deadlines, including the frequency with which re-authorizations are required:

### Cigna

### <u>Inpatient</u>

Cigna typically authorizes 1-4 medical/surgical or MH/SUD inpatient days upon pre-service review.

B. Forms and/or other information required to be submitted by the provider:

### Cigna

### Inpatient

For a inpatient to prior authorization, the enrollee's treating provider submits a request for benefit authorization of an inpatient level of care electronically or by phone, fax or mail. If the request cannot be authorized using an approved algorithm, the case is referred to a nurse reviewer/care manager who collects and reviews the supporting clinical information for medical necessity. If the nurse reviewer/care manager determines the enrollee meets criteria for the inpatient level of care requested, he/she authorizes the services at issue.

C. Utilization management manuals and any other documentation of UM

## Step 4(a): Briefly describe the processes by which Prior Authorization is applied to MH/SUD benefits:

A. Timelines and deadlines, including the frequency with which re-authorizations are required:

### Cigna

Same as M/S

B. Forms and/or other information required to be submitted by the provider:

### Cigna

Same as M/S

C. Utilization management manuals and any other documentation of UM

<sup>&</sup>lt;sup>20</sup> This section is responsive to Requirements 5-7 in FAQ Part 45 at 4.

processes that are relied upon to make a determination:

### Cigna

Services covered under a Cignaadministered benefit plan, including M/S benefits, may require Prior Authorization to achieve a variety of objectives, including the verification of the appropriate utilization of services by type/level of care and place/setting of service under benefit plans administered by Cigna, as well as verification that a service will be rendered for a covered benefit.

When determining which M/S In Network benefits are subject to pre-service medical necessity review (prior authorization/precertification), Cigna conducts at least annually, a Precertification Code Review Procedure by the Total Health and Network Operations and Medical Economics Coverage Policy, Precertification Team ("Precertification Team"). Precertification Team workgroup leaders include Coding Team Supervisors, the Total Health and Network Operations ("THN") Medical Director and ad hoc members including Cigna Medical Directors and subject matter expertise with the ability to exercise professional judgement. The Precertification Team makes a final recommendation to the THN medical and clinical leadership, a final determination is made and the Precertification List is updated, operationalized and provider notifications are communicated.

D. In-operation processes in place to make a determination such as distinctions between first and secondlevel reviews or between administrative

processes that are relied upon to make a determination:

### Cigna

Same as M/S

D. In-operation processes in place to make a determination such as distinctions between first and secondlevel reviews or between administrative and clinical reviews, peer-to-peer reviews, and the use of medical discretion applied in lieu of or in the absence of written criteria and guidelines:

### Cigna

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for the request, he/she refers the case to a peer reviewer (e.g. Medical Director) who reviews the clinical information and determines whether the enrollee meets medical necessity criteria for the request (i.e., peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). Cigna typically authorizes 1-4 M/S or MH/SUD inpatient days upon preservice review.

#### Peer to Peer Review Variation

With respect to MH/SUD benefits, and in contrast to the process for performing M/S benefit reviews, Cigna ensures that any potential denial of MH/SUD benefits is preceded by a proactive offer to the provider of a peer-to-peer review for certain services in the Inpatient benefit classifications. The objectives of proactively seeking a peer-to-peer review is to minimize the risk of issuing a denial where, in fact, the enrollee's clinical situation warrants an approval for medically necessary care yet the provider's request may have incompletely or imprecisely stated the case for medical necessity, or, if a denial is nonetheless issued, mitigating disruption if the loss of coverage results in the enrollee moving to a different treatment type or level of care. This process is

and clinical reviews, peer-to-peer reviews, and the use of medical discretion applied in lieu of or in the absence of written criteria and guidelines:

### Cigna

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for the request, he/she refers the case to a peer reviewer (e.g. Medical Director) who conducts a peer-to-peer review with the treating provider. The peer reviewer reviews the clinical information and determines whether the enrollee meets medical necessity criteria for the request (i.e., peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). Cigna typically authorizes 1-4 M/S or MH/SUD inpatient days upon preservice review.

Peer to Peer Review Variation – Same as M/S see analysis in M/S column

beneficial for the enrollee and results in greater approvals and fewer appeals of medical necessity denials.

Cigna's medical necessity review of MH/SUD services is guided by the ASAM Criteria, MCG and Cigna's Clinical Coverage policies and plan documents approved for use in care management determinations. Ciana's Peer-to-Peer review program is triggered when a care manager receives clinical information that does not appear to meet the ASAM Criteria, MCG and Cigna's Clinical Coverage policies and plan documents for initial or prior authorization for level of care requested. In this instance, care managers may offer a lower level of care to ensure there is no delay or impediment to care where the medical necessity criteria is met. If that level of care is not accepted by the requesting provider (treating practitioner), the case is referred to Peer-to-peer review with a behavioral health physician reviewer.

The Peer-to-Peer review is available for any coverage request for which Cigna anticipates issuing a denial Cigna incorporates into its MH/SUD utilization review process a requirement that – prior to issuing a denial – a Cigna clinician proactively solicit a peer-to-peer review with the rendering provider. After completing the peer-to-peer review with the rendering provider, the Ciana Medical Director makes a decision to approve or deny the requested service, based on all of the clinical information provided. Peer-to-peer reviews that are declined by the requesting provider result in the Cigna Medical Director making a decision to approve or deny the requested service based on the clinical information that was submitted and

obtained by the Cigna clinician. All reconsideration and appeal options are available if a case results in a denial, just as they are available for denials issues for an M/S request.

If Cigna's pro-active, volunteer Peer-to-Peer review were not applicable to MH/SUD services, and such services followed a similar process to the M/S benefit, services that were approved due to such Peer-to-Peer review, would have been much more likely to have resulted in a denial without additional information or discussion to meet clinical criteria. The provider has the right to decline the peer review and move forward retaining the same rights post-decision/denial. Cigna's pro-active Peer-to-Peer review is more favorable to the enrollee and the rendering/requesting provide resulting in a less stringent, more advantageous process for MH/SUD claims because it is proactive, as compared to the process for M/S claims whereby any peer-to-peer review is, unless otherwise required by state law, conducted reactively, i.e., if the rendering provider outreaches to Cigna.

Cigna has not identified any additional discrepancies in operational policies between MH/SUD and M/S benefits where the discrepancies present a comparability or stringency problem within the context of the NQTL requirement. Instances where discrepancies between the process of administering MH/SUD and M/S benefits do not present an NQTL issue include, for example, situations where a discrepancy in process is more advantageous to the administration of MH/SUD benefits than M/S benefits such as the pro-active behavioral health peer-to-peer review

process outlined herein. The Peer-to-Peer analysis is addressed in the "in operation" section of this submission set forth below.

Ciana also reviewed the ROIs for both MH/SUD and M/S non-emergent inpatient admissions. For the purposes of the ROI calculation, the estimated costs to perform a coverage review, which is informed by costs/expenses for personnel salaries and time to review. Cigna reviewed the ROI for both M/S and MH/SUD non-emergent inpatient admissions. M/S services for nonemergent inpatient admissions calculated at 9:1 for 2019, 8:0 for 2020 and 10:1 for partial year 2021 and ROIs for MH/SUD services for non-emergent inpatient admissions calculated at 2.93:1 for 2019, 2.05:1 for 2020 and 2.03:1 for partial year 2021 respectively. These calculations are consistent with the factor/evidentiary standard outlined in Steps 2 and 3, namely that the application of prior authorization to inpatient M/S benefits produces a positive savings for both MH/SUD and M/S benefits, as measured in the aggregate across the Cigna-administered book-ofbusiness. To be clear, if the number preceding the colon is greater than 1 (e.g., 2.93), then the application of prior authorization produces a positive ROI and thus meets the evidentiary standard for application of the same to MH/SUD or M/S inpatient benefits.

Additionally, Cigna conducts routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) testing is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Corrective action is initiated if

a score falls below 85% and if the results are below 90% the Medical Director will evaluate the scores and decide whether to convene a review process with the Medical Directors/Physician Reviewers. Of note, the company's most recent MH/SUD IRR exercise did not reveal a need to revise its coverage policies governing reviews of MH/SUD benefits.

E.. Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification):

### Cigna

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for the request, he/she refers the case to a peer reviewer (e.g. Medical Director) who reviews the clinical information and determines whether the enrollee meets medical necessity criteria for the request (i.e., peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). See "Peer to Peer Review Variation" section above for additional details and analysis related to Cigna's peer-to-peer review process.

Final adverse determinations of medical/surgical services and MH/SUD services are made in accordance with evidence-based treatment guidelines by physician peer reviewers licensed in the same or similar specialty area as the treating provider.

E. Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification):

### Cigna

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for the request, he/she refers the case to a peer reviewer (e.g. Medical Director) who conducts a peer-to-peer review with the treating provider. The peer reviewer reviews the clinical information and determines whether the enrollee meets medical necessity criteria for the request (i.e., peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). See "Peer to Peer Review Variation" section for additional details and analysis related to Ciana's peer-topeer review process.

Final adverse determinations of medical/surgical services and MH/SUD services are made in accordance with evidence-based treatment guidelines by physician peer reviewers licensed in the

same or similar specialty area as the treating provider.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization for M/S benefits:

**2023 Data** – Wellfleet delegates Utilization Management, including Prior Authorization, to Cigna. The below data represents an analysis of prior authorization requests across Wellfleet's Book of Business from January 1, 2023 – December 31, 2023.

### **Inpatient Prior Authorization Denial Rates**

NETWORK	INN	OON
Auth Type	Precert	Precert
MED SURG	64	3
Approvals	48	1
Denials	16	2
MedSurg % Denied	25%	67%

The data above shows that 25% of inpatient in-network prior authorizations were denied and 67% of inpatient out-of-network prior authorizations were denied.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization for MH/SUD benefits:

**2023 Data** – Wellfleet delegates Utilization Management, including Prior Authorization, to Cigna. The below data represents an analysis of prior authorization requests across Wellfleet's Book of Business from January 1, 2023 – December 31, 2023.

### **Inpatient Prior Authorization Denial Rates**

NETWORK	INN	OON
Auth Type	Precert	Precert
MH	8	3
Approvals	8	3
Denials	0	0
MH % Denied	0%	0%
SUD	2	2
Approvals	2	2
Denials	0	0
SUD % Denied	0%	0%

The data above shows that 0% of MH & SUD prior authorizations were denied in both inpatient in-network and out-of-network classifications. This is less stringent

### **Appeals Data**

### Inpatient

Network	INN	OON
Auth Type	Precert	Precert
MedSurg	0	1
Denials Upheld	0	0
Denials Overturned	0	1
MedSurg % Upheld	0%	0%

The data above shows one denial overturned.

compared to the 19% of Med/Surg inpatient in-network prior authorizations denied, and also to the 67% of Med/Surg inpatient out-of network prior authorizations denied. Therefore, the percentage of denials for MH/SUD services is comparable to, and not more stringent than, the percentage of denials for Med/Surg prior authorization requests.

### **Appeals Data**

### Inpatient

Network	INN	OON
Auth Type	Precert	Precert
MH	0	2
Denials Upheld	0	2
Denials Overturned	0	0
MH % Upheld	0%	100%
SUD	0	0
Denials Upheld	0	0
Denials Overturned	0	0
SUD % Upheld	0%	0%

The data above shows all MHSUD denials upheld. This is less stringent compared to the denial overturned for MedSurg. The MHSUD services are comparable and less stringent than that of MedSurg.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage,

### including any results that indicate that the plan or coverage is or is not in compliance with this section

• 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<sup>21</sup>

**As written:** All sources, evidentiary standards, and other factors used to apply PA to MH/SUD benefits, as written, are <u>the same</u> as the sources, evidentiary standards, and other factors used to apply PA to M/S benefits in the classification as written.

Cigna has assessed several components of its utilization management program for NQTL compliance, including the methodology for determining which services will be subject to utilization management, the process for reviewing utilization management requests, and the process for applying coverage criteria. A review of Cigna's written policies and processes reveals the comparable process by which MH/SUD and M/S services are selected for application of prior authorization within the applicable benefit classification the evidences comparability and equivalent stringency inwriting and in-operation.

First, a committee of Cigna-employed Medical Directors determines which M/S and MH/SUD services shall be subject to prior authorization or concurrent review. To the extent any MH/SUD services within the inpatient classification is considered for inclusion on the "precertification list" a Cigna-employed Medical Director with former practice experience as a psychiatrist and expertise in, and dedicated support for, behavioral health matters is consulted to ensure appropriate evaluation of MH/SUD services that may be considered for application of prior authorization and concurrent review.

Cigna's MTAC – which includes representation across a number of disciplines, including MH/SUD expertise – approves any implementation of, or changes to, coverage policies used to make medical necessity determinations to ensure the appropriateness of the same. The inclusion of appropriate representation of MH/SUD expertise in the coverage policy development process ensures that coverage policies for MH/SUD benefits appropriately incorporate generally-accepted standards of practice, including consideration of type or duration of treatment or level of care for patients with specific MH/SUD conditions.

Comparable representation of expertise in MH/SUD services is therefore ensured to the extent any MH/SUD benefits may be considered for inclusion on the precertification list, thus ensuring comparable reviews of MH/SUD benefits. Moreover, the list of services subject to prior authorization and concurrent review is reviewed no less frequently than annually to determine if any services, whether MH/SUD or M/S, should be removed or added to the list, so the frequency of review

<sup>&</sup>lt;sup>21</sup> This section is responsive to Requirement 8 in FAQ Part 45 at 4.

of the continued appropriateness of application of prior authorization is comparable across MH/SUD and M/S benefits.

Cigna does not use different factors or evidentiary standards, or use the same factor and evidentiary standard differently, when reviewing MH/SUD and M/S benefits for continued inclusion on the prior authorization list. Because the benefit or value of conducting pre-service review of the treatment type outweighs the administrative costs associated with conducting the review, the treatment type is subject to preservice medical necessity review (prior authorization).

**In Operation:** As demonstrated by the data outlined in Step 4(b), an "in operation" review of Wellfleet Cigna's application of the Prior Authorization NQTL, specifically approvals and denial information, in the inpatient classification revealed no statistically significant discrepancies in denial rates between MH/SUD and M/S benefits. While operational outcomes are not determinative of NQTL compliance, and an insurer may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement. Consequently, Cigna concludes that the NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

### Denial rates

Specifically, as shown in Step 4(b) above, for the inpatient in-network and out-of-network classifications, the prior authorization denial rate data above shows that 0% of MH/SUD prior authorizations were denied in both inpatient in-network and out-of-network classifications. This is less stringent compared to the 25% of Med/Surg inpatient in-network prior authorizations denied, and also to the 67% of Med/Surg inpatient out-of-network prior authorizations denied. Therefore, the percentage of denials for MH/SUD services is comparable to, and not more stringent than, the percentage of denials for Med/Surg prior authorization requests. In fact, the denial rate for MH/SUD prior authorization services is far lower than the denial rate for Med/Surg prior authorization denial rates, showing MH/SUD services are treated more favorably.

### Appeal rates

In comparing the M/S and MH/SUD data, very few denials were appealed (only 2 denials were appealed for MH/SUD and only 1 denial was appealed for M/S services). Although there were very few appeals, it is of note that the MHSUD appeals were upheld and the MedSurg denial was overturned. This shows the services for MHSUD is comparable to, and not more stringent than, the percentage of appeals overturned for MedSurg.

The process by which services are considered for application of Prior Authorization is comparable in writing and in operation across MH/SUD and M/S benefits, as

evidenced by Wellfleet Cigna's assessment of several components of the prior authorization determination process in the overall context of its utilization management programs.

**Conclusion**: Wellfleet has determined that PA is applied for MH/SUD benefits in a manner that is comparable to and no more stringent than that of M/S services, both as written and in operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose PA.

### **NQTL: Prior Authorization**

### Classification(s): Prescription Drugs

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Prior Authorization and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Provide a clear description of the specific NQTL, plan terms, and policies at issue:22

From Wellfleet's standard Certificate of Coverage Template: Prior Authorization (Preauthorization) is a decision by Wellfleet's delegated Utilization Review Organization, prior to a member's receipt of a Covered Service, procedure, treatment plan, device, or Prescription Drug that the Covered Service, procedure, treatment plan, device or Prescription Drug is Medically Necessary. For the purposes of this NQTL, the plan considers Prior Authorization of clinical reviews for determining medical necessity and not administrative reviews.

Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Prior Authorization NQTL and the guidelines that drive the decisions by ESI are approved by Wellfleet's internal Pharmacy and Therapeutics Committee (P&T) and Value Assessment Committee (VAC).

See P&T Policy, where it states: "Prior Authorization: A decision made prior to a member's receipt and coverage of a Prescription Drug to determine that the Drug is Medically Necessary and being utilized appropriately."

\_

<sup>&</sup>lt;sup>22</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

## Identify the M/S benefits/services for which Prior Authorization is required:<sup>23</sup>

Please see attached (Covered Services Attachment) which details benefits subject to PA

### Identify the MH/SUD benefits/services for which Prior Authorization is required:<sup>24</sup>

Please see attached (Covered Services Attachment) which details benefits subject to PA

Step 2 – Identify the factors used to determine that Prior Authorization will apply to mental health or substance use disorder benefits and medical or surgical benefits<sup>25</sup>

### Medical/Surgical:

Factors for determining whether a prescription drug product will have Prior Authorization or not:

- 1. Lack of adherence to quality standards
- 2. High variability in cost within drugs in a given therapeutic class
- 3. Anticipated excessive utilization
- 4. Member Impact (this factor is used only to determine when PA should not be applied)

### MH/SUD:

Factors for determining whether a prescription drug product will have Prior Authorization or not:

1. Same as M/S

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Prior Authorization to mental health or substance use disorder benefits and medical or surgical benefits.

### Medical/Surgical:

A. Factors for determining whether to apply PA:

- Factor 1: lack of adherence to quality standards – This factor carries more weight due to the safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  - Sources: FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peerreviewed medical literature.
  - Evidentiary Standard: P&T
     Committee members discuss safety

### MH/SUD:

A. Factors for determining whether to apply PA:

- Factor 1: lack of adherence to quality standards – This factor carries more weight due to the safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  - Sources: FDA
     Prescribing Information,
     professionally
     recognized treatment
     guidelines used to define
     clinically appropriate
     standards of care such
     as ASAM criteria or APA

 $<sup>^{\</sup>rm 23}$  This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>24</sup> Id

<sup>&</sup>lt;sup>25</sup> This section is responsive to Requirement 3 in *FAQ Part 45* at 4.

of newly released products to determine if they have potential for unsafe use. Sources listed above are compiled by Wellfleet's Clinical Pharmacist into New Drug Reviews and Therapeutic Class Reviews. These reviews contain information on indications, dosing & administration, clinical and comparative efficacy, clinical guidelines, contraindications & special populations, etc. These are forwarded to the P&T committee prior to the meetings for their review. Meeting discussions include an analysis of: appropriate dosing. potential overdose, prescribing by particular specialty provider, adherence or potential nonadherence to guidelines, etc.

- Factor 2: high variability in cost within drugs in a given therapeutic class
  - Sources: First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis
  - Evidentiary Standard: High cost is defined as \$670/month supply. Also taken into account are the availability of alternate therapies (brand/generic) & lowest total net cost for course of therapy for given conditions.
- Factor 3: anticipated excessive utilization
  - Source: Aggregated data or nonidentifiable utilization reports, FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.
  - Evidentiary Standard: Clinical Pharmacist reviews claims data every 6 months and compares actual utilization against the recommendations in the sources

- treatment guidelines, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peerreviewed medical literature.
- Evidentiary Standard:
   Same as M/S

- Factor 2: high variability in cost within drugs in a given therapeutic class
  - Sources: First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis
  - Evidentiary Standard: Same as M/S
- Factor 3: anticipated excessive utilization
  - Source: Aggregated data or non-identifiable utilization reports. FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as ASAM criteria or APA treatment guidelines, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-

identified above (e.g. FDA prescribing information, dosing schedules, etc.) to determine whether a drug is being used excessively or inappropriately. "Excessive utilization" is defined as anything above the FDA approved dosing schedule or recommended dosage in peer-reviewed medical iournals. If the Clinical Pharmacist determines a drug is subject to potential excessive utilization, the Clinical Pharmacist or the P&T Committee may recommend applying prior authorization to the Value Assessment Committee (VAC). The VAC reviews the Clinical Pharmacist's and the P&T Committee recommendation to approve the decision of applying prior authorization.

- Factor 4: Member Impact (this factor is used only to determine when PA should not be applied)
  - Source: Internal claims data, internal market and competitive analysis
  - o Evidentiary Standard: The Value Assessment Committee runs a cost report for the past year to determine the impact and number of members that maybe be using a particular benefit that is being considered for PA application. The VAC determines the number of members that will be negatively impacted by prior authorization additions. The VAC makes a decision based on their professional judgement as to whether PA should not be applied to avoid negative member impact. This is only taken into account to decide not to apply or to remove a Prior Authorization requirement from a medication and is not used in the application process for PA. If factors 1, 2, and 3 suggest the addition of PA, but we anticipate significant member or client impact based on our covered demographic, we would

- reviewed medical literature.
- Evidentiary Standard:
   Same as M/S

- Factor 4: Member Impact (this factor is used only to determine when PA should not be applied)
  - Source: Internal claims data, internal market and competitive analysis
  - Evidentiary Standard:
     Same as M/S

put the interest of our members first and not assign a PA designation.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

Timelines and deadlines, including the frequency with which re-authorizations are required:

- Turnaround times for review and either approving or denying a PA request are based on state requirements. However, on average across Wellfleet's book of business PA requests are processed within 1 business day.
- Authorizations for both M/S and MHSUD drugs are valid for 365 days from approval. Approvals may be for a shorter duration if the FDA labeling guidelines have strict duration of therapy limits or monitoring requirements after initiation. Other exceptions are for products that have regulatory implications, which will be approved based on the regulatory statute.
- Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance.

Forms and/or other information required to be submitted by the provider:

- Providers can request Prior Authorizations by calling Express Scripts Prior Authorization department directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a Prior Authorization Request Form and faxing directly to Express Scripts Prior Authorization department.
- Providers may be required to submit lab/test results for approval. This

Timelines and deadlines, including the frequency with which re-authorizations are required:

Same as M/S

Forms and/or other information required to be submitted by the provider:

requirement is based off of requirements laid out in the FDA labeling information or Clinical Guidelines specific to the diagnoses that the particular drug product in question is indicated for. For example, the use of Humira has a weight minimum for particular indications. Documentation of the patient's weight is required in order to get approval for this product. Also, narcolepsy without cataplexy should be confirmed via Epworth Sleepiness Scales. Xyrem, a product indicated for this diagnosis, requires documentation of this test being performed and indicating the correct diagnosis.

Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination:

- All Prior Authorization guidelines (M/S and MH/SUD) are gathered into one PDF document that is available to members, providers, and the general public. It is posted at https://wellfleetrx.com/students/formularies/. This publication is updated at least quarterly.
- The P&T Policy & Procedures and Formulary Management Policy are reviewed by Wellfleet's Chief Medical Officer, Director of Clinical Programs, and Clinical Pharmacist, at least annually to ensure there is no verbiage indicating a bias towards any particular subset of drugs. These policies dictate that all decisions should be based off of the clinical merits of the drug, not the classification of drug itself. Prior authorization is imposed on drug products based on the factors presented previously for both classifications of drugs. In the review of the P&T policy, it is stated that "The clinical decisions made by the P&T Committee are based on sound scientific evidence and standards of practice that include: 1. Assessing peerreviewed medical literature. 2. Referencing published practice guidelines. 3. Comparing efficacy, side effects, and potential drug

Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination:

interactions among alternative drug therapies. 4. Assessing impact of formulary decisions to patient compliance." There is also the presence of a non-discriminatory section, stating that members shall not "discriminate based on age, disability, race, ethnicity, gender, sexual orientation, or health status." Members non-adhering to either of these statements will be recused from the committee. No recusals have been a result of non-adherence to these policies.

### Relevant Decision Making Committees

- P&T Committee
  - The P&T Committee is responsible for assessing the clinical merits of drug therapies. The committee shall provide clinical rationale and guidance on formulary placement. The Value Assessment Committee (VAC) follows the P&T Committee recommendations to finalize formulary placement decisions.
  - The P&T Committee is responsible for approving any new Utilization Management policies (guidelines) or negative changes (any change creating a larger barrier to member access) to these guidelines. If a quideline change includes any criteria that differs from the FDA approved labeling information, it will also require justification and approval from the P&T Committee. Guidelines shall also be reviewed annually for approval. At each P&T meeting, the new, updated, and a quarter of all other quidelines will be discussed and approved/denied.
- Value Assessment Committee (VAC)
  - The VAC is responsible for determining tiering and Utilization Management decisions for drugs that are designed as 'include' by the P&T Committee. These drugs shall not be removed from formulary without prior approval from the P&T Committee. Also, determining

### Relevant Decision Making Committees

coverage, tiering, and Utilization Management decisions for drugs that are designated as 'optional' by the P&T Committee.

Minimum qualifications for reviewers:

- To become members of the P&T
   Committee, the physicians must be board
   certified licensed physicians with over 5
   years of experience in their respective
   fields. We use the clinical expertise of the
   P&T Committee members along with
   published clinical guidelines and scientific
   evidence to achieve consensus in order to
   set Prior Authorization.
- Every PAR, UMP, Nurse, and Medical Director goes through extensive training to make sure we are providing the most complete and comprehensive service for each one of our members. The training consists of both in classroom, on the job shadowing, monthly quality reviewing of cases, and weekly meetings to provide any new/updated information that needs to be shared with the teams.

Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification):

- In lieu of drug specific Prior Authorization criteria, or prior to the creation of drug specific criteria, if a drug is designated as "PA Required", we will utilize our "Guideline for Drugs without PA Criteria" to make a determination of approval. This guideline requires that the requested medication be used for an indication that is approved by the FDA or listed in the package insert, and that the patient meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information.
- If a member does not meet requirements laid our in Prior Authorization guidelines, they will be issued a denial. If the member elects to appeal, they will be asked to

Minimum qualifications for reviewers:

• Same as M/S

Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification):

submit further documentation in support of use of the product (ex. case-studies supporting use, off-label usage recommended in clinical guidelines, etc). This process is the same for both M/S and MH/SUD drugs.

 Depending on state requirements, a denial may only be issued by certain individuals with particular qualifications (e.g. physician with same/similar specialty licensed in the same state, pharmacist, etc.). This is kept consistent for M/S and MH/SUD.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization for M/S benefits:

To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to M/S drugs, prior authorization (PA) for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to prior authorization. See table below for M/S results.

M/S PA Requirements	
Total M/S Drugs	8,742
Total M/S Drugs Requiring PA	1,753
PA Required Rate	20%

 We also completed an analysis of the turnaround times for PA requests to be issued either an approval or denial. On To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to M/S drugs. prior authorization (PA) for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to prior authorization. See table below for MH/SUD results.

MH/SUD PA Requirements	
Total MH/SUD Drugs	772
Total MH/SUD Drugs Requiring PA	48
PA Required Rate	6.2%

- average, the turnaround time for M/S drugs was less than 1 day
- We also completed an analysis of denial rates for requests for Prior Authorization in calendar year 2022. Results can be seen in the table below. Most recent Interrater reliability results for reviews performed were 93.94% for M/S reviews.

Global M/S PA Analysis	
Total PA Requests	2648
Total PA Approvals	1857
Total PA Denials	791
PA Approval Rate	70.1%
PA Denial Rate	29.9%

MD M/S PA Analysis	
Total PA Requests	2
Total PA Approvals	2
Total PA Denials	0
PA Approval Rate	100%
PA Denial Rate	0%

- We also completed an analysis of the turnaround times for PA requests to be issued either an approval or denial. On average, the turnaround time for MH/SUD drugs was less than 1 day.
- We also completed an analysis of denial rates for requests for Prior Authorization in calendar year 2022. Results can be seen in the table below. Most recent Interrater reliability results for reviews performed were 90.53% for MH/SUD reviews.

Global MH/SUD PA Analysis	
Total PA	247
Requests	241
Total PA	205
Approvals	205
Total PA	42
Denials	42
PA Approval	83%
Rate	03%
PA Denial Rate	17%

MD MH/SUD PA Analysis	
Total PA	0
Requests	U
Total PA	0
Approvals	U
Total PA Denials	0
PA Approval	N/A
Rate	IN/A
PA Denial Rate	N/A

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

**As written:** The process for creating a prior authorization policy for a drug is the same for both M/S and MH/SUD drugs. The P&T Policy & Procedures and Formulary Management Policy are reviewed by Wellfleet's Chief Medical Officer, Director of Clinical Programs, and Clinical Pharmacist, at least annually to ensure there is no verbiage indicating a bias towards any particular subset of drugs. These policies dictate that all decisions should be based off of

the clinical merits of the drug, not the classification of drug itself. Prior authorization is imposed on drug products based on the factors presented previously for both classifications of drugs.

Prior authorization is imposed on drug products based on the factors presented in Steps 2 &3 for both classifications of drugs. These include the drug's lack of adherence to quality standards, high variability in cost within drugs in a given therapeutic class, anticipated excessive utilization and member Impact. Whether each factor is met is based upon defined evidentiary standards, which are based upon FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), peer-reviewed medical literature, internal market and competitive analysis, therapeutic class total net cost analysis, aggregated data or non-identifiable utilization reports, internal claims data, internal market and competitive analysis. The factors, standards and sources for those standards are the same regardless of whether a drug is a M/S or MH/SUD drug.

Moreover, a request for prior authorization is subject to the same review process for both M/S and MH/SUD drugs. Authorizations for both M/S and MHSUD drugs are valid for 365 days from approval. Approvals may be for a shorter duration if the FDA labeling guidelines have strict duration of therapy limits or monitoring requirements after initiation. Other exceptions are for products that have regulatory implications, which will be approved based on the regulatory statute. Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Prior Authorization to MH/SUD drugs, <u>as written</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Prior Authorization to M/S drugs.

**In operation:** In operation, the percentage of MH/SUD drugs requiring prior authorization (6.2%) is much lower than the percentage of M/S drugs requiring prior authorization (20%). The denial rate for MH/SUD drug requests (0%; or N/A) is the same as the denial rate for M/S drug requests (0%). The virtual absence of appeals for MH/SUD drugs and M/S drugs indicates that benefit determinations and denials for MH/SUD drugs are in fact performed in a manner that is equally as stringent as determinations and denials for M/S drugs. Given that the same reviewers are used for both MH/SUD and M/S drug requests, IRR scores cannot be differentiated for comparative purposes, but the very high score averages (each above 90%) also suggest that reviews are consistent across all requests.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Prior Authorization to MH/SUD drugs, <u>in operation</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Prior Authorization to M/S drugs.

**Conclusion**: Wellfleet has determined that PA is applied for MH/SUD drugs in a manner that is comparable to and no more stringent than that of M/S drugs, both as written and in

operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose PA.

### 3. Concurrent Review Process

#### **NQTL: Concurrent Review**

Classification(s): Inpatient In-Network, Inpatient Out-Of-Network

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Concurrent Review and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Step 1(a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:26

Concurrent Review is a decision made during the course of care that the Covered Services are Medically Necessary.

Wellfleet delegates its non-Pharmacy Utilization Management to Cigna. Cigna is responsible for determining which non-Pharmacy benefits are eligible for Concurrent Review. As such, Cigna's utilization management policies are used to determine Concurrent Review factors, sources and evidentiary standards. Once the benefits subject to Concurrent Review are determined, Cigna performs utilization management on Wellfleet's behalf. Their policies are used to determine operational aspects of Concurrent Review.

Step 1(b): Identify the M/S
benefits/services for which Concurrent
Review is required:27

Step 1(b): Identify the MH/SUD benefits/services for which Concurrent Review is required:28

Inpatient IN Network and Out of Network

Inpatient IN Network and Out of Network

Step 2 – Identify the factors used to determine that Concurrent Review will apply to mental health or substance use disorder benefits and medical or surgical benefits29

Medical/Surgical:	MH/SUD:
A. Factors for determining whether to apply CR:	Same as M/S

<sup>&</sup>lt;sup>26</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>27</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>29</sup> This section is responsive to Requirement 3 in FAQ Part 45 at 4.

Wellfleet delegates its Utilization Management, including Concurrent Review, to Cigna. As such, Wellfleet utilizes Cigna's factors for determining when to apply CR.

Services covered under а Cignaadministered benefit plan, including M/S benefits, may require Concurrent Review to achieve a variety of objectives, includina the verification of appropriate utilization of services by type/level of care and place/setting of service under benefit plans administered by Cigna, as well as verification that a service will be rendered for a covered benefit. Services covered under a benefit medical or behavioral administered by Cigna that are on-going with multiple services over multiple dates of service beyond the initial period for which coverage was approved may be subject to Concurrent Review to confirm level of care and clinical appropriateness.

A Service may be subject to Concurrent Review, when such Service requires (1) the ongoing assessment to determine or continue to establish the medical necessity of continued services; and (2) appropriateness of current level of care for the severity; or (3) one or more of the following:

- Complexity of the condition and if extension, expansion, or reduction of services is appropriate based on nationally recognized guidelines
- Expected timeframe for clinical response/outcomes based on literature
- Efficacy of the treatment modality
- Progress toward goals of therapy
- Discharge / transition planning

## B. Factors for determining whether to remove CR:

Once Wellfleet receives the list of services subject to CR from Cigna, Wellfleet can choose to remove CR from certain benefits/ services. Wellfleet uses the following factors to determine whether to remove CR from certain services:

- 1. ROI
- 2. School preference/ selection (used only to remove CR)

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Concurrent Review to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.<sup>30</sup>

### Medical/Surgical:

# A. Factors for determining whether to apply CR:

#### Sources

- Industry accepted procedures codes developed by:
  - American Medical
     Association (AMA) publication
     of the Current Procedural
     Terminology (CPT) book
  - American Hospital Association (AHA) publication of revenue codes
  - American Formulary
     Association (AFA) publication of codes
  - Centers for Medicare and Medicaid Services (CMS) publication of codes
- Internal claims data
- UM program operating costs

### MH/SUD:

# A. Factors for determining whether to apply CR:

#### Sources

<sup>&</sup>lt;sup>30</sup> This section is responsive to Requirements 3 and 4 in FAQ Part 45 at 4.

- UM authorization data
- Expert Medical Review of Clinical Criteria
- Nationally recognized evidencebased guidelines

### **Evidentiary Standards**

The evidentiary standard relied on to determine whether to apply Concurrent Review to inpatient MH/SUD and M/S benefits is whether application of Concurrent Review produces positive financial savings, as measured in the aggregate across the Cigna-administered book-of-business. The value associated with inpatient benefit reviews, as calculated by reference to the expected financial savings relative to the costs to review benefit claims, is assessed at the classification level and not at a service/procedure level.

Cigna has determined the value of subjecting all inpatient In-Network and Out-of-Network M/S services to Concurrent Review must exceed the administrative costs by at least 1:1. The Concurrent Review NQTL applies to all M/S services. The administration is identical.

## Consideration of Step Therapy/Fail First Requirements

Cigna imposes step therapy and/or fail first requirements on certain M/S services including for example, MRI, gastric bypass, lumbar spine fusion where higher-cost therapies may be denied unless it can be shown that a lower-cost therapy is not effective (also known as "fail-first" policies or "step therapy" protocols).

### B. Factors for determining whether to remove CR:

- Factor 1: Return on investment
   Source:
  - Wellfleet claims data,

### **Evidentiary Standards**

Same as M/S

## Consideration of Step Therapy/Fail First Requirements

Same as M/S, except Cigna does not impose a Fail First/Step Therapy NQTL on MH/SUD services where higher-cost therapies may be denied unless it can be shown that a lower-cost therapy is not effective (also known as "fail-first" policies or "step therapy" protocols).

### B. Factors for determining whether to remove CR:

- Charges by delegated Review Organization to perform Concurrent Review on add-on services
- o Evidentiary Standard: ROI<1 is required to remove a benefit from the list. ROI is defined as annual savings from Prior Auth divided by annual cost (PMPMx12) charged by delegated Review Organization to perform Prior Authorization on add-on services
- Factor 2: School (client) preference
  - Source: School (client) decision to remove a benefit from the list\*
  - Evidentiary Standard: PA will be removed if the school (client) states that they do not want a certain benefit to be subject to PA and:
    - (a) that preference is negotiated as part of the sales process, or
    - (b) that preference is provided in writing in an independent decision by the school (client) at a later date

\*Plans reviewed by Cigna have no Prior Authorization for any outpatient MH/SUD benefit as the ROI for Prior Authorization review by Cigna of all outpatient MH/SUD services is <1.

\*School (client) preference is generally to provide a better benefit for the student and/or ease student administrative burden with their health plan; finance is not a consideration. It is applied uniformly to M/S and MH/SUD benefits. As noted above, this wouldn't apply to any MH/SUD benefit for plans delegated to Cigna for Prior Authorization review.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.<sup>31</sup>

# Step 4(a): Briefly describe the processes by which Concurrent Review is applied to M/S benefits:

Timelines and deadlines, including the frequency with which re-authorizations are required:

Initiating Inpatient Concurrent Care Review

This occurs when a facility/provider requests to extend an inpatient stay beyond the previously authorized length of stay or more frequently based upon review of the level of care and clinical criteria. For M/S benefits, the nurse reviewer/care manager collects the updated clinical information and/or reviews it for medical necessity. If the nurse

# Step 4(a): Briefly describe the processes by which Concurrent Review is applied to MH/SUD benefits:

Timelines and deadlines, including the frequency with which re-authorizations are required:

Initiating Inpatient Concurrent Care Review – Same as M/S

<sup>&</sup>lt;sup>31</sup> This section is responsive to Requirements 5-7 in FAQ Part 45 at 4.

reviewer/care manager determines the enrollee meets criteria for continued inpatient care, he/she authorizes the services at issue.

### Criteria

Cigna uses MCG Guidelines for ambulatory care, inpatient and surgical care, recovery facility care, home care, and behavioral health care for coverage guidance in utilization review of services that are not addressed in a Cigna medical, or co-branded coverage policy.

### Higher Review

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for continued inpatient care, he/she refers the case to a peer reviewer (e.g. Medical Director) who reviews the clinical information and determines whether the enrollee meets criteria for continued inpatient care (i.e. peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). Cigna typically authorizes 1-4 M/S inpatient days upon concurrent care review. (See Peer to Peer Variation Analysis in Medical Necessity Section).

### Peer to Peer Review Variation

With respect to MH/SUD benefits, and in contrast to the process for performing M/S benefit reviews, Cigna ensures that any potential denial of MH/SUD benefits is preceded by a proactive offer to the provider of a peer-to-peer review for certain services including Inpatient and Outpatient All Other benefit classifications. The objectives of proactively seeking a peer-to-peer review is to minimize the risk of issuing a denial where, in fact, the enrollee's

### Criteria

Cigna uses MCG for non-SUD primary diagnosis of behavioral health level of care and Cigna uses ASAM Criteria for coverage guidance in utilization review level of care of SUD services.

### Higher Review

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for continued inpatient care, he/she refers the case to a peer reviewer (e.g. Medical Director) who conducts a peer-to-peer review with the treating provider. The peer reviewer reviews the clinical information and determines whether the enrollee meets criteria for continued inpatient care (i.e. peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). Ciana typically authorizes 1-6 MH/SUD inpatient days upon concurrent care review. (See Peer to Peer Variation Analysis in Medical Necessity Section).

Peer to Peer Review Variation – Same as M/S (see analysis in M/S column)

clinical situation warrants an approval for medically necessary care yet the provider's request may have incompletely or imprecisely stated the case for medical necessity, or, if a denial is nonetheless issued, mitigating disruption if the loss of coverage results in the enrollee moving to a different treatment type or level of care. This process is beneficial for the enrollee and results in greater approvals and fewer appeals of medical necessity denials.

Cigna's medical necessity review of MH/SUD services is guided by the ASAM Criteria, MCG and Ciana's Clinical Coverage policies and plan documents approved for use in care management determinations. Cigna's Peer-to-Peer review program is triggered when a care manager receives clinical information that does not appear to meet the ASAM Criteria, MCG and Ciana's Clinical Coverage policies and plan documents for initial or prior authorization for level of care requested. In this instance, care managers may offer a lower level of care to ensure there is no delay or impediment to care where the medical necessity criteria is met. If that level of care is not accepted by the requesting provider (treating practitioner), the case is referred to Peer-to-peer review with a behavioral health physician reviewer.

The Peer-to-Peer review is available for any coverage request for which Cigna anticipates issuing a denial Cigna incorporates into its MH/SUD utilization review process a requirement that – prior to issuing a denial – a Cigna clinician proactively solicit a peer-to-peer review with the rendering provider. After completing the peer-to-peer review with the rendering provider, the Cigna

Medical Director makes a decision to approve or deny the requested service, based on all of the clinical information provided. Peer-to-peer reviews that are declined by the requesting provider result in the Cigna Medical Director making a decision to approve or deny the requested service based on the clinical information that was submitted and obtained by the Cigna clinician. All reconsideration and appeal options are available if a case results in a denial, just as they are available for denials issues for an M/S request.

If Ciana's pro-active, volunteer Peer-to-Peer review were not applicable to MH/SUD services, and such services followed a similar process to the M/S benefit, services that were approved due to such Peer-to-Peer review, would have been much more likely to have resulted in a denial without additional information or discussion to meet clinical criteria. The provider has the right to decline the peer review and move forward retaining the same rights post-decision/denial. Cigna's pro-active Peer-to-Peer review is more favorable to the enrollee and the rendering/requesting provide resulting in a less stringent, more advantageous process for MH/SUD claims because it is proactive, as compared to the process for M/S claims whereby any peer-to-peer review is, unless otherwise required by state law, conducted reactively, i.e., if the rendering provider outreaches to Cigna.

Cigna has not identified any additional discrepancies in operational policies between MH/SUD and M/S benefits where the discrepancies present a comparability or stringency problem within the context of the NQTL

requirement. Instances where discrepancies between the process of administering MH/SUD and M/S benefits do not present an NQTL issue include, for example, situations where a discrepancy in process is more advantageous to the administration of MH/SUD benefits than M/S benefits such as the pro-active behavioral health peer-to-peer review process outlined herein. The Peer-to-Peer analysis is addressed in the "in operation" section of this submission set forth below.

Cigna regularly reviews utilization management data to evaluate and ensure operational compliance of the medical management suite of NQTLs, including Medical Necessity and Appeals, Prior Authorization and Concurrent Review. Data is reviewed by benefit classification and subclassification to calculate denial rates to ensure comparability. Ciana's application of the medical necessity NQTL, specifically approvals and denials rates, for Prior Authorization, Retrospective Review, and Concurrent Review across benefit classifications for a sampling of Cigna plans revealed no statistically significant discrepancies in medical necessity denial rates asbetween MH/SUD and M/S benefits. Cigna utilizes appeals data to review the number of utilization review decisions across the book-of-business. Appeals data is delineated by pre and post services and includes prior authorization and concurrent review, overturned for the same time period relating to the utilization management data metrics included in Cigna's book of business data. Data reflected overall comparable overturn rates across benefit classifications.

While the rate of appeals, where the original denial for lack of medical necessity was upheld, is higher for MH/SUD than for M/S claims, this appeal rate, coupled with the utilization management data reflecting higher Medical Necessity denial rates for M/S claims than for MH/SUD claims is representative of Cigna's proactive approach to peer-to-peer review.

Additionally, Cigna conducts routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) testing is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Corrective action is initiated if a score falls below 85% and if the results are below 90% the Medical Director will evaluate the scores and decide whether to convene a review process with the Medical Directors/Physician Reviewers. Of note, the company's most recent MH/SUD IRR exercise did not reveal a need to revise its coverage policies governing reviews of MH/SUD benefits.

The number of utilization review decisions across the Wellfleet Cigna book of business data, reflects substantially higher denial rates based upon Medical Necessity across all benefit classifications for utilization management programs including prior authorization, concurrent review and retrospective review with medical necessity denials for M/S services on average higher than medical necessity denials of MH/SUD services. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD

benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the inoperation component of the NQTL requirement.

Minimum qualifications for reviewers:

UM coverage determinations of M/S services are made in accordance with evidence-based treatment guidelines by physician peer reviewers licensed in the same or similar specialty area as the treating provider.

Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification):

If the nurse reviewer/care manager determines the enrollee meets criteria for continued inpatient care, he/she authorizes the services at issue.

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for continued inpatient care, he/she refers the case to a peer reviewer (e.g. Medical Director) who reviews the clinical information and determines whether the enrollee meets criteria for continued inpatient care (i.e. peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). Cigna typically authorizes 1-4 M/S inpatient days upon concurrent care review. (See Peer to Peer Variation Analysis in Section above).

Minimum qualifications for reviewers – Same as M/S

Minimum standards to issue a denial (e.g. sign-off from a physician with relevant board certification):

If the nurse reviewer/care manager determines the enrollee meets criteria for continued inpatient care, he/she authorizes the services at issue.

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for continued inpatient care, he/she refers the case to a peer reviewer (e.g. Medical Director) who conducts a peer-to-peer review with the treating provider. The peer reviewer reviews the clinical information and determines whether the enrollee meets criteria for continued inpatient care (i.e. peer reviewer may authorize or deny benefit authorization depending upon the information provided by the treating provider). Cigna typically authorizes 1-6 MH/SUD inpatient days upon concurrent care review. (See Peer to Peer Variation Analysis in Section above).

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Concurrent Review for M/S benefits:

2023 Data – Wellfleet delegates Utilization Management, including Prior Authorization, to Cigna. The below data represents an analysis of concurrent review requests across Wellfleet's Book of Business from January 1, 2023 – December 31, 2023.

### **Inpatient Prior Authorization Denial Rates**

NETWORK	INN	OON
Auth Type	Concurre nt	Concurre nt
MED SURG	628	6
Approvals	505	4
Denials	123	2
MedSurg % Denied	20%	33%

The data above shows that 20% of inpatient in-network prior authorizations were denied and 33% of inpatient out-of-network concurrent reviews were denied.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Concurrent Review for MH/SUD benefits:

**2023 Data** – Wellfleet delegates Utilization Management, including Prior Authorization, to Cigna. The below data represents an analysis of concurrent review requests across Wellfleet's Book of Business from January 1, 2023 – December 31, 2023.

### **Inpatient Prior Authorization Denial Rates**

UR Service	Innt	Innt
Level	Inpt	Inpt
NETWORK	INN	OON
Auth Type	Concurre nt	Concurre nt
WH	713	146
Approvals	709	141
Denials	4	5
MH % Denied	1%	3%
SUD	33	65
Approvals	33	64
Denials	0	1
SUD % Denied	0%	2%

The data above shows that 0% of MH & SUD concurrent reviews were denied in inpatient in-network and 2% denied in out-of-network classifications. This is less stringent compared to the 20% of Med/Surg inpatient in-network concurrent denied, and also to the 33% of Med/Surg inpatient out-of network concurrent denied. Therefore, the percentage of denials for MH/SUD

### Appeals Data – Inpatient

There were no concurrent review appeals noted across Wellfleet Cigna book-of-business

services is comparable to, and not more stringent than, the percentage of denials for Med/Surg prior authorization requests.

### Appeals Data – Inpatient

There were no concurrent review appeals noted across Wellfleet Cigna book-of-business.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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<sup>32</sup>

**As written:** All sources, evidentiary standards, and other factors used to apply CR to MH/SUD benefits, as written, are <u>the same</u> as the sources, evidentiary standards, and other factors used to apply CR to M/S benefits in the classification as written.

Cigna applies the Concurrent Review NQTL consistently to M/S benefits and MH/SUD benefits. In both M/S and MH/SUD services, concurrent care reviews are typically initiated by a nurse reviewer for M/S benefits or Care Manager (licensed behavioral health clinician) for MH/SUD benefits telephonically a day or two before the last covered/authorized day.

Inpatient services reimbursed on the basis of a DRG/case rate and otherwise authorized pursuant to a prior authorization review are not subject to concurrent review because, for the duration of the period for which the DRG/case rate applies, the amount of benefits the plan is obligated to pay for a facility stay does not depend on the duration of time that the individual received care in the facility. DRG-based reimbursement creates incentives for hospitals to actively manage utilization but DRG-based fees do not exist for psychiatric hospitalizations. The lack of correlation between the length of stay and the plan's obligation to pay benefits for the same means that assessing the ongoing medical necessity of a continued facility stay for coverage/benefit purposes is unnecessary for such period of time.

The case rate/DRG payment functions as payment in full for any and all services rendered to the individual for the pre-authorized course of treatment for the length of time covered by the case rate/DRG payment and over which the individual remains in the facility. The plan's liability for payment of benefits for services, and the individuals' cost-sharing obligation, does not increase or decrease depending on how long the individual remains in the facility receiving the pre-authorized treatment in question, unless the individual's stay extends beyond the time period that the DRG/case rate payment covers.

\_\_\_

<sup>&</sup>lt;sup>32</sup> This section is responsive to Requirement 8 in FAQ Part 45 at 4.

DRG-based reimbursement creates incentives for hospitals to actively manage utilization but DRG-based fees do not exist for psychiatric hospitalizations. Concurrent Review by Cigna is clinically appropriate and permissible for psychiatric hospitalizations as general medical hospitalizations that are not reimbursed based on DRGs are also subject to concurrent review. Differences in utilization management of inpatient behavioral health is not a more stringent application because DRG-based fees have not been established for psychiatric hospitalizations.

**In Operation:** As shown in Step 4(b) above, for the inpatient in-network and out-of-network classifications, the concurrent denial rate data above shows that 0% and 2% of MH/SUD concurrent reviews respectively were denied in inpatient in-network and out-of-network classifications. This is less stringent compared to the 20% of Med/Surg inpatient in-network prior authorizations denied, and also to the 33% of Med/Surg inpatient out-of-network prior authorizations denied. Therefore, the percentage of denials for MH/SUD services is comparable to, and not more stringent than, the percentage of denials for Med/Surg prior authorization requests. In fact, the denial rate for MH/SUD prior authorization services is far lower than the denial rate for Med/Surg prior authorization denial rates, showing MH/SUD services are treated more favorably.

A review of concurrent review appeals data revealed no appeals for either medsurg nor MHSUD.

Cigna's methodology for determining which M/S services and which MH/SUD services within a classification of benefits are subject to concurrent care review as written and in operation, as well as its concurrent care medical necessity review processes applied to M/S services and for MH/SUD services as written and in operation reflect they are comparable and no more stringent for MH/SUD services within a classification of benefits than for M/S services within the same classification of benefits.

**Conclusion**: Wellfleet has determined that concurrent review is applied for MH/SUD benefits in a manner that is comparable to and no more stringent than that of M/S services, both as written and in operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose concurrent review.

### 4. Retrospective Review Process

### **NQTL: Retrospective Review**

**Classification(s):** Inpatient, In-Network; Outpatient, In-Network (including applicable sub-classifications); Inpatient, Out-of-Network; and Outpatient, Out-of-Network (including applicable sub-classifications).

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Retrospective Review and a description of all mental health or substance use disorder

### and medical or surgical benefits to which each such term applies in each respective benefits classification

# Step 1 (a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:<sup>33</sup>

Define Retrospective Review:

Retrospective Review, as a form of utilization management, is considered a non-quantitative treatment limitation ("NQTL") under the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") and its implementing regulations and sub-regulatory guidance.

Wellfleet delegates its non-Pharmacy Utilization Management to Cigna. Cigna is responsible for determining which non-Pharmacy benefits are eligible for retrospective review. As such, Cigna's utilization management policies are used to determine retrospective review factors, sources, and evidentiary standards. Once the benefits subject to retrospective review are determined, Cigna and Wellfleet perform utilization management on Wellfleet's behalf. Their policies are used to determine operational aspects of retrospective review.

Cigna defines Retrospective Review as its review of a claim after a service has already been provided, but before the claim for that service has been paid. Specifically, these are reviews of coverage authorizations that were not approved prior to the service being rendered. Cigna does not incorporate language related to Retrospective Review in its certificate or benefits booklet.

All non-emergent M/S and MH/SUD inpatient and outpatient services are theoretically subject to a medical necessity review. Cigna also employs the same definition of medical necessity to medical/surgical (M/S) and mental health/substance use disorder (MH/SUD) benefits.

Cigna Medical Directors apply the definition of "medical necessity" set forth in the governing plan instrument or the definition required by state law. In general, Cigna uses the following definition:

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;

<sup>&</sup>lt;sup>33</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

- not primarily for the convenience of the patient, Physician or other health care provider;
- 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, all elements of Medical Necessity must be met as specifically outlined in the individual's benefit plan documents, 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.

# Step 1 (b): Identify the M/S benefits/services for which Retrospective Review is required:<sup>34</sup>

The same services subject to Concurrent Review and Prior Authorization are also subject to Retrospective Review

### Step 1 (b): Identify the MH/SUD benefits/services for which Retrospective Review is required:35

The same services subject to Concurrent Review and Prior Authorization are also subject to Retrospective Review

## Step 2 – Identify the factors used to determine that Retrospective Review will apply to mental health or substance use disorder benefits and medical or surgical benefits<sup>36</sup>

### Medical/Surgical:

A. Factors for determining whether to apply RR:

 Whether the service is determined to be experimental/investigational/unprov en

#### MH/SUD:

A. Factors for determining whether to apply RR:

<sup>&</sup>lt;sup>34</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>35</sup> Id

<sup>&</sup>lt;sup>36</sup> This section is responsive to Requirement 3 in *FAQ Part 45* at 4.

- 2. Whether the service is/may be excluded from coverage
- 3. Whether the service presents a serious risk to enrollee safety
- 4. Whether the service demonstrates significant variations from evidence-based care
- 5. Whether there is a high incidence of fraud, waste, and/or abuse
- 6. Whether the service is associated with a high average cost
- 7. Performing coverage reviews for a service is projected to meet or exceed a certain return on investment ratio
- B. Factors for determining whether to remove RR

Once Wellfleet receives the list of services subject to RR from Cigna, Wellfleet can choose to remove RR from certain benefits/ services. Wellfleet uses the following factors to determine whether to remove RR from certain services:

- 1. ROI
- 2. School preference/ selection (used only to remove RR)

B. Factors for determining whether to remove RR:

Same as M/S

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Retrospective Review to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.<sup>37</sup>

<sup>&</sup>lt;sup>37</sup> This section is responsive to Requirements 3 and 4 in FAQ Part 45 at 4.

### Medical/Surgical:

- A. Factors for determining whether to apply RR:
- Whether the service is determined to be experimental/investigational/unprov en

Evidentiary Standard: A service is considered to be EIU if an assessment of available clinical evidence establishes any of the following:

- Inadequate volume of existing peer-reviewed, evidence-based, scientific literature to establish whether or not 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 approval by an Institutional Review Board for the proposed use except as provided in a clinical trial; or
- the subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials.
- 2. Whether the service is/may be excluded from coverage Evidentiary Standard: Cigna assesses whether the plan/policy excludes from coverage a

### MH/SUD:

A. Factors for determining whether to apply RR:

particular service, or for a particular use. Specifically, a service may be rendered for one or more uses covered by a benefit plan and one or more uses that are excluded by the benefit plan, or the intended use of the service cannot be identified based on the information provided in a submitted benefit claim. For example, benefit plan may exclude a service if it is rendered for cosmetic purposes, but the benefit plan may cover a service if it is rendered to treat a covered condition. The clinically appropriate uses for a service are determined through an assessment of available Clinical Evidence for the service.

- 3. Whether the service presents a serious risk to enrollee safety

  Evidentiary Standard: Whether a service presents a serious risk to enrollee safety is determined through an assessment of available Clinical Evidence for the service. Examples of safety issues considered to be potentially life-threatening include a service such as rapid detoxification under anesthesia, or the use of a service that is the subject of a serious warning or recall.
- 4. Whether the service demonstrates significant variations from evidence-based care

  Evidentiary Standard: A variation in evidence-based care must reflect a statistically significant standard deviation from the standard frequency or duration in treatment using the service, while accounting for operational and knowledge variations that may exist across providers and geographic areas.

- What is considered statisticallysignificant will vary by the type of service, as the frequency or duration in treatment standard may vary by service type.
- 5. Whether there is a high incidence of fraud, waste, and/or abuse

  Evidentiary Standard: identified in publications by organizations that track trends regarding fraud waste, and abuse in utilization of healthcare services.
- 6. Whether the service is associated with a high average cost.

  Evidentiary Standard: Based on an assessment of Cigna's historical paid claims for the service across its commercial book of business, the average unit cost of the service must exceed five hundred dollars (\$500), unless either:
  - a. The service is an unlisted or non-specific code where the unit cost may vary from far less than \$500 to far more than \$500; or
  - b. The service is associated with serial use where the cumulative average use of the services may be represented by a single prior authorization and therefore exceed the dollar threshold.
- Performing coverage reviews for a service is projected to meet or exceed a certain return on investment ratio.
   <u>Evidentiary Standard</u>: The ROI ratio is calculated using the following formula:
  - a. The actual or anticipated denial rate of the service multiplied by the average unit cost (or, as applicable,

- cumulative cost) of the service, with the resulting figure divided by the estimated cost to review the total number of services.
- b. For services for which Cigna maintains historic claims data, Ciana calculates the denial rate by reference to the actual denial rate as reflected in the historic bookof-business claims data it maintains. The average unit cost of the service is calculated based on Cigna's historical paid claims for the service across its commercial book of business. The estimated cost to perform a coverage review is \$100 per review, which is informed by costs/expenses such as personnel salaries and time.

#### Sources:

When developing coverage criteria to evaluate the medical necessity of services, Cigna's Coverage Policy Unit (CPU), in partnership with Ciana's Medical Technology Assessment Committee, conducts evidence-based assessments of the medical literature and other sources of information pertaining to the safety and effectiveness of medical and behavioral health services, therapies, procedures, devices, technologies and pharmaceuticals. The Medical Technology Assessment Committee's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as set forth below in Cigna's "Levels of Scientific Evidence Table" adapted from the Centre for Evidence Based Medicine, University of Oxford:

- Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.
- Level 2: Non-randomized controlled trials (an experimental study, but not an ideal design). Also systematic reviews and meta-analyses of nonrandomized controlled trials.
- Level 3: Observational studies e.g. cohort, case-control studies (nonexperimental studies). Also systematic reviews and metaanalyses of observational studies.
- Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also systematic reviews and metaanalyses of retrospective studies.
- Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.

"Clinical evidence" as referenced above includes publications from professional societies that include nationally recognized specialists in the appropriate field (e.g., American College of Obstetricians and Gynecologists); guidance published by appropriate Government Regulatory Agencies (e.g., CMS, FDA, NIH); and other original research studies, publish in the English language, peer reviewed, published, evidence-based scientific studies or literature.

Notably, the above-stated standards used to apply the factors described in Step 2 may not in each case be associated with a specific quantitative threshold at which the NQTL is triggered, as not every factor lends itself to simply quantitative assessment. Rather, the quantitative factors mentioned above in each case requires subject matter experts like clinicians to qualitatively assess publications that do not define the factors relied on by Cigna to design its NQTLs in a numerical threshold or formula. By contrast, the quantitative factors that Ciana considers when deciding whether to apply authorization to MH/SUD and M/S benefits are defined by reference to specific thresholds at which the factor is met.

- B. Factors for determining whether to remove RR:
  - Factor 1: Return on investment
    - Evidentiary Standard: ROI<1 is required to remove a benefit from the RR list. ROI of a specific service type is calculated as follows:
  - Wellfleet (through its Chief Medical Officer and Finance Department) determines the annual savings from authorization by adding up all approved charges for a specific service type using the initial ICD-10 code (to identify M/S vs. MH/SUD) and & specified CPT codes (to identify a specific service type) that were requested but denied and not overturned on appeal
  - Then, Wellfleet determines the annual cost of authorization for a specified service type as follows:
  - For each month of the year,
     Wellfleet multiplies Cigna's per member per month charge for retrospective review of the specified

B. Factors for determining whether to remove RR:

- service type, times the number of members in all the plans delegated to Cigna for utilization review that month.
- Wellfleet adds the costs above for all twelve (12) months together to yield the total annual cost of authorization of that specified service type
- Wellfleet determines the ROI of a specified service type by dividing the total annual savings by the total annual costs for that specified service type.
  - If ROI is < 1, retrospective review will be removed from the service
- Source:
  - Wellfleet claims data
    Charges by delegated Review
    Organization to perform
    Retrospective Review on add-on
    services
- Factor 2: School (client) preference [Note: this factor is only used to remove Retrospective Review from MH/SUD benefits, and is never used to apply RR to MH/SUD benefits, thus this factor only serves to make MH/SUD benefits more accessible to members by potentially eliminating RR from certain MH/SUD services].
  - Evidentiary Standard: RR will be removed if the school (client) states that they do not want a certain benefit to be subject to RR and:
    - (a) that preference is negotiated as part of the sales process, or
       (b) that preference is provided in writing in an independent decision by the school
       (client) at a later date.
- Source: School (client) decision to remove a benefit from the list\*

\*Plans reviewed by Cigna have no Retrospective Review for any outpatient MH/SUD benefit as the ROI for Retrospective Review by Cigna of all outpatient MH/SUD services is <1.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.<sup>38</sup>

## Step 4(a): Briefly describe the processes by which Retrospective Review is applied to M/S benefits:

\*Note: Since the plan defines retrospective review as an authorization post service but pre-payment, the processes for retrospective review are the same as the processes outlined by the plan in the Prior Authorization NQTL.

A. Timelines and deadlines, including the frequency with which re-authorizations are required:

#### Cigna

# Step 4(a): Briefly describe the processes by which Retrospective Review is applied to MH/SUD benefits:

\*Note: Since the plan defines retrospective review as an authorization post service but pre-payment, the processes for retrospective review are the same as the processes outlined by the plan in the Prior Authorization NQTL.

A. Timelines and deadlines, including the frequency with which reauthorizations are required:

#### Cigna

<sup>&</sup>lt;sup>38</sup> This section is responsive to Requirements 5-7 in FAQ Part 45 at 4.

Cigna typically authorizes 1-4 medical/surgical or MH/SUD inpatient days upon review.

B. Forms and/or other information required to be submitted by the provider:

#### Cigna

For a service subject to retrospective review, the enrollee's treating provider submits a request for benefit authorization of an inpatient level of care electronically or by phone, fax or mail. If the request cannot be authorized using an approved algorithm, the case is referred to a nurse reviewer/care manager who collects and reviews the supporting clinical information for medical necessity. If the nurse reviewer/care manager determines the enrollee meets criteria for the inpatient level of care requested, he/she authorizes the services at issue.

C. In-operation processes in place to make a determination such as distinctions between first and second-level reviews or between administrative and clinical reviews, peer-to-peer reviews, and the use of medical discretion applied in lieu of or in the absence of written criteria and quidelines:

#### Cigna

If the nurse reviewer/care manager assesses the enrollee does not appear to meet medical necessity criteria for the inpatient level of care at issue, he/she refers the case to a peer reviewer (e.g. Medical Director) who reviews the clinical information and determines whether the enrollee meets medical necessity criteria for the inpatient level of care at issue (i.e., peer reviewer may authorize or deny benefit authorization depending upon the

B. Forms and/or other information required to be submitted by the provider:

#### Cigna

Same as M/S

C. In-operation processes in place to make a determination such as distinctions between first and second-level reviews or between administrative and clinical reviews, peer-to-peer reviews, and the use of medical discretion applied in lieu of or in the absence of written criteria and quidelines:

#### Cigna

information provided by the treating provider).

Cigna regularly reviews utilization management data to evaluate and ensure operational compliance of the medical management suite of NQTLs, including Medical Necessity and Appeals, Prior Authorization and Concurrent Review. Data is reviewed by benefit classification and sub-classification to calculate denial rates to ensure comparability. Cigna's application of the medical necessity NQTL, specifically approvals and denials rates, for Prior Authorization, Retrospective Review, and Concurrent Review across benefit classifications for a sampling of Cigna plans revealed no statistically significant discrepancies in medical necessity denial rates as-between MH/SUD and M/S benefits. Cigna utilizes appeals data to review the number of utilization review decisions across the book-of-business. Appeals data is delineated by pre and post services and includes prior authorization and concurrent review, overturned for the same time period relating to the utilization management data metrics included in Ciana's book of business data. Data reflected overall comparable overturn rates across benefit classifications.

Additionally, Cigna conducts routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) testing is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Corrective action is initiated if a score falls below 85% and if the results are below 90% the Medical Director will evaluate the scores and decide whether to convene a review process with the Medical

Directors/Physician Reviewers. Of note, the company's most recent MH/SUD IRR exercise did not reveal a need to revise its coverage policies governing reviews of MH/SUD benefits.

D. Minimum qualifications for reviewers:

#### Cigna

Coverage determinations of medical/surgical services and MH/SUD services are made in accordance with evidence-based treatment guidelines by physician peer reviewers licensed in the same or similar specialty area as the treating provider.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization for M/S benefits:

**2023 Data** – Wellfleet delegates Utilization Management, including retrospective review, to Cigna. The below data represents an analysis of retrospective review requests across Wellfleet's Book of Business from January 1, 2023 – December 31, 2023.

#### **Inpatient Prior Authorization Denial Rates**

UR Service Level	Inpt	Inpt
NETWORK	INN	OON
Auth Type	Retro	Retro
MED SURG	348	4
Approvals	255	3
Denials	93	1
MedSurg % Denied	27%	25%

D. Minimum qualifications for reviewers:

#### Cigna

Coverage determinations of medical/surgical services and MH/SUD services are made in accordance with evidence-based treatment guidelines by physician peer reviewers licensed in the same or similar specialty area as the treating provider.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization for MH/SUD benefits:

2023 Data – Wellfleet delegates
Utilization Management, including
retrospective review, to Cigna. The
below data represents an analysis of
retrospective review requests across
Wellfleet's Book of Business from January
1, 2023 – December 31, 2023.

#### **Inpatient Prior Authorization Denial Rates**

UR Service		
Level	Inpt	Inpt
NETWORK	INN	OON
Auth Type	Retro	Retro
MH	22	5
Approvals	20	5
Denials	2	0
MH % Denied	<b>9</b> %	0%
SUD	1	0

The data above shows that 27% of inpatient in-network retrospective reviews were denied and 25% of inpatient out-of-network retrospective reviews were denied.

#### **Appeals Data**

#### **Inpatient**

Network	INN	OON
Auth Type	Retro	Retro
MedSurg	29	11
Denials Upheld	21	2
Denials Overturned	8	9
MedSurg % Upheld	72%	18%

The data above shows that 72% of inpatient in-network retrospective reviews were upheld and 18% of inpatient out-of-network retrospective reviews were upheld.

Approvals	1	0
Denials	0	0
SUD % Denied	0%	0%

The data above shows that 9% of MH were denied retrospectively in inpatient in-network and 0% out-of-network classifications. This is less stringent compared to the 27% of Med/Surg inpatient in-network retrospective reviews denied, and also to the 25% of Med/Surg inpatient out-of-network retrospective reviews denied. Therefore, the percentage of denials for MH/SUD services is comparable to, and not more stringent than, the percentage of denials for Med/Surg prior authorization requests.

#### **Appeals Data**

#### Inpatient

Network	INN	OON
Auth Type	Retro	Retro
MH	0	1
Denials Upheld	0	1
Denials Overturned	0	0
MH % Upheld	0%	100%
SUD	0	0
Denials Upheld	0	0
Denials Overturned	0	0
SUD % Upheld	0%	0%

The data above shows all MHSUD denials upheld. This is less stringent compared to the denials overturned for MedSurg. The MHSUD services are comparable and less stringent than that of MedSurg.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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<sup>39</sup>

#### As written:

Cigna has assessed several components of its utilization management program for NQTL compliance, including the methodology for determining which services will be subject to utilization management, the process for reviewing utilization management requests, and the process for developing coverage criteria.

Cigna's methodology for determining which medical/surgical services and which MH/SUD services within a classification of benefits are subject to concurrent review as written and in operation, as well as its concurrent medical necessity review processes applied to medical/surgical services and for MH/SUD services as written and in operation reflect they are comparable and no more stringent for MH/SUD services within a classification of benefits than for medical/surgical services within the same classification of benefits.

#### In operation:

As demonstrated by the data outlined in Step 4(b), an "in operation" review of Wellfleet Cigna's application of the Retrospective Review NQTL, specifically approvals and denial information, in the inpatient classification revealed no statistically significant discrepancies in denial rates between MH/SUD and M/S benefits. While operational outcomes are not determinative of NQTL compliance, and an insurer may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement. Consequently, Cigna concludes that the NQTL

<sup>&</sup>lt;sup>39</sup> This section is responsive to Requirement 8 in FAQ Part 45 at 4.

was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

Findings conclusions:

The comparative analysis performed for application of Retrospective Review to inpatient benefits evidence compliance with the MHPAEA NQTL requirement, in writing and in operation. Cigna's analysis of the process and policies governing the application of Retrospective Review across MH/SUD and M/S benefits, as well as the process by which MH/SUD and M/S services are selected for application of Retrospective Review, evidences comparability and equivalent stringency, in writing and in operation. The written process, the trigger for application of Retrospective Review, and the medical necessity standard used to review services subject to Retrospective Review, comparable across MH/SUD and M/S benefits, but the assessment of denial rates across Wellfleet's plans do not reveal any potential "warning signs" warranting further assessment and/or changes to how the Retrospective Review NQTL is designed or applied to MH/SUD benefits.

The factor and its accompanying evidentiary standard used to determine whether Concurrent Review will apply to an inpatient or outpatient service pursuant to the above-described process, namely the ROI metric, is likewise uniform for MH/SUD and M/S benefits. Wellfleet does not use different factors or evidentiary standards, or use the same factor and evidentiary standard differently, when reviewing MH/SUD and M/S benefits for continued inclusion on the list of services subject to Retrospective Review. Wellfleet methodology for determining which M/S services and which MH/SUD services within a classification of benefits are subject Retrospective Review as written and in operation, as well as its medical necessity review processes, are no more stringent for MH/SUD services than for M/S services within the same classification of benefits.

Wellfleet has determined that Retrospective Review is applied for MH/SUD benefits in a manner that is comparable to and no more stringent than that of M/S services, both as written and in operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose Retrospective Review.

#### 5. Process for Assessment of New Technologies

**NQTL: Experimental and Investigational Determinations** 

Classification(s): Inpatient, Outpatient, and Emergency

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Experimental and Investigational Determinations and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

#### Step 1(a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:40

"Experimental/Investigative" means the service or supply has not been demonstrated in scientifically valid clinical trials and research studies to be safe and effective for a particular indication.

Wellfleet does not cover any health care service, procedure, treatment, device, or Prescription Drug that is experimental or investigational, unless Our denial is overturned by an External Appeal Agent.

"Experimental, investigational and unproven (EIU) services" are medical, surgical, diagnostic, or other health care technologies, supplies, treatments, procedures, drug therapies or devices that are determined by Cigna's Coverage Policy Unit (CPU), in partnership with Cigna's Medical Technology Assessment Committee, to be:

- not demonstrated through or an inadequate volume of, existing peerreviewed, evidence-based, scientific literature to be safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;
- not approved by the U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency to be lawfully marketed for the proposed use;
- the subject of review or approval by an Institutional Review Board for the proposed use except as provided in the "Clinical Trials" section(s) 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" section(s) of this plan.

Wellfleet delegates its non-Pharmacy Utilization Management to Cigna. Cigna is responsible for determining which non-Pharmacy benefits are eligible for E/I review. As such, Cigna's utilization management policies are used to determine E/I factors, sources and evidentiary standards. Their policies are used to determine operational aspects of E/I, and are addressed in this NQTL accordingly.

#### Step 1(b): Identify the M/S benefits/services to which Experimental and Investigational Determinations is applied:41

The evaluation of Experimental, Investigational and Unproven ("EIU") services are applicable to all M/S services, regardless of benefit classification.

#### Step 1(b): Identify the MH/SUD benefits/services to which Experimental and Investigational Determinations is applied:42

The evaluation of Experimental, Investigational and Unproven ("EIU") services are applicable to all MH/SUD services, regardless of benefit classification.

<sup>42</sup> Id.

<sup>&</sup>lt;sup>40</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>41</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

Step 2 – Identify the factors used to determine that Experimental and Investigational Determinations will apply to mental health or substance use disorder benefits and medical or surgical benefits<sup>43</sup>

#### Medical/Surgical:

Cigna considers the following factors in determining whether a services is experimental, investigational or unproven:

- inadequate volume of existing peerreviewed, evidence-based, scientific literature to establish whether or not 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 approval by an Institutional Review Board for the proposed use except as provided in the in a clinical trial
- 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.

#### MH/SUD:

Same as M/S

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Experimental and Investigational Determinations to mental health or substance use disorder benefits and medical or surgical benefits.

 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.

<sup>&</sup>lt;sup>43</sup> This section is responsive to Requirement 3 in *FAQ Part 45* at 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.<sup>44</sup>

#### Medical/Surgical:

#### Sources

In approving new technology, MTAC uses principles of evidence-based medicine in its evaluation of the following sources:

- clinical literature
- FDA approval or clearance, as appropriate, is necessary, but not sufficient, for Cigna to consider a technology to be proven.
- FDA approval or clearance
- English language peer reviewed publications including documents prepared by specialty societies and evidence-based review centers, such as the Agency for Health Care Research and Quality.

#### Evidentiary Standard.

Levels of evidence are assigned to the publications based upon underlying study characteristics, including but not limited to incidence and prevalence of disease, study design, number of subjects, clinical outcomes of relevance, statistics used and significance, and assessment of flaws and bias. A research team performs a synthetic assessment of the literature to determine if there is a sufficiently evidence based proven relationship between the intervention and improved health outcomes.

Cigna considers other sources of internal and external information as part of its decision-making process including input from health care professionals and other interested parties. Health care professionals may share their comments

#### MH/SUD:

<sup>&</sup>lt;sup>44</sup> This section is responsive to Requirements 3 and 4 in FAQ Part 45 at 4.

with the regional market medical executive representing a specific geography, account or subject matter issue. The information is reviewed as part of the annual update process.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.<sup>45</sup>

#### Step 4(a): Briefly describe the processes by which Treatments are determined to be E/I for M/S benefits

#### **Delegation to Cigna**

Wellfleet delegates non-Pharmacy
Utilization Management to Cigna. Cigna
is responsible for determining which nonPharmacy benefits are eligible for E/I
review. As such, Cigna's utilization
management policies are used to
determine E/I factors, sources and
evidentiary standards. Their policies are
used to determine operational aspects of
E/I.

Cigna collects, tracks and trends relevant metrics on a semi-annual basis for

Step 4(a): Briefly describe the processes by which Treatments are determined to be E/I for MH/SUD benefits

<sup>&</sup>lt;sup>45</sup> This section is responsive to Requirements 5-7 in *FAQ Part 45* at 4.

services within each classification of medical/surgical and MH/SUD benefits. Metrics may include initial EIU coverage denials, coverage denials upheld and overturned upon internal appeal and coverage denials upheld and overturned upon external appeal/review.

## Relevant Committee for Determining E/I – Committee Composition and Processes

Cigna's Medical Technology Assessment Committee (MTAC) applies a consistent process in the development of evidence-based Coverage Policies for a wide variety of medical technologies. The MTAC committee is composed of physicians and nurses, and includes specialists from assorted medical and behavioral health disciplines.

MTAC is composed of physicians and nurses, and includes specialists from assorted medical and behavioral health disciplines.

MTAC 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, OBGYNs, oncologists, primary care physicians, internists, surgeons, urologists, pulmonologists, cardiologists, and psychiatrists.

The committee reviews (i) FDA approval/clearance status, (ii) English language peer reviewed publications; and (iii) relevant documents prepared by specialty societies and evidence-based review centers and uses principles of evidence-based medicine in its evaluation of clinical literature and in its deliberative process and in preparing

published medical coverage polices. The MTAC committee develops criteria to assist medical directors in determining whether a service/device is deemed to be medically necessary or experimental, investigational or unproven.

#### Step 4(b): Briefly describe the processes by which coverage determinations or exceptions are made for E/I Treatments for M/S services

N/A – there are no exceptions to the E/I determination process

# Step 4(c): Identify and define the factors and processes that are used to monitor and evaluate the application of E/I Treatment policies for M/S services

Cigna collects, tracks and trends relevant metrics on a semi-annual basis for services within each classification of M/S and MH/SUD benefits. Metrics may include initial EIU coverage denials, coverage denials upheld and overturned upon internal appeal and coverage denials upheld and overturned upon external appeal/review.

#### 2023 Data -

#### **Utilization Management**

Wellfleet delegates Utilization Management to Cigna. The data represents an analysis of prior, concurrent, and retrospective review authorization requests across Wellfleet's Book of Business from January 1, 2023 – December 31, 2023.

The number of utilization review decisions across the Wellfleet - Cigna book of business data noted above, reflects significantly less denial rates on average across all benefit classifications for

#### Step 4(b): Briefly describe the processes by which coverage determinations or exceptions are made for E/I Treatments for MH/SUD services

N/A – there are no exceptions to the E/I determination process

Step 4(c): Identify and define the factors and processes that are used to monitor and evaluate the application of E/I Treatment policies for MH/SUD services

utilization management for MHSUD including prior authorization, concurrent review and retrospective review for medical necessity denials. MedSurg services denials are significantly higher than medical necessity denials of MH/SUD services.

#### Claims

Overall, Wellfleet's Claims Summary Data revealed 64 claims denied for E/I out of 41749 denials or <1% for MHSUD. For MedSurg, there were 22 claims denied for E/I out of 112105 denials or <1%. This demonstrates that MHSUD is no more stringent for MH/SUD services within a classification of benefits than for M/S services within the same classification of benefits. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the inoperation component of the NQTL requirement.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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<sup>46</sup>

<sup>&</sup>lt;sup>46</sup> This section is responsive to Requirement 8 in *FAQ Part 45* at 4.

**As written**: The definition of experimental/investigational /unproven services is the same for MS and MH/SUD. A single review committee, Cigna's MTAC evaluates all new technologies for M/S and MH/SUD benefits. Cigna's methodology and processes for determining whether M/S interventions and MH/SUD interventions within a classification of benefits are experimental, investigational and/or unproven are comparable and no more stringent for MH/SUD services within a classification of benefits than for M/S services within the same classification of benefits as written and in operation.

The use of MTAC for development of evidence based Coverage Policies for M/S and MH/SUD demonstrates as written and in operation reflect they are comparable and no more stringent for MH/SUD services.

**In operation**: An "in operation" review of claims data from Wellfleet plans revealed no excessive denial rates for MH/SUD claims denied as experimental, investigational and unproven as compared to M/S claims denied as experimental, investigational and unproven. An "in operation" review of Cigna's application of the Experimental, Investigational, and Unproven NQTL, specifically approvals and denial information, in the "All Other Outpatient, Out-of-Network, Services" classification revealed no statistically significant discrepancies in EIU denial rates as-between MH/SUD and M/S benefits.

While operational outcomes are not determinative of NQTL compliance, and an insurer may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement. Consequently, Cigna concludes that the NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

**Findings conclusions**: The application of the same NQTL standard across M/S and MH/SUD benefits demonstrates as written and in operation reflect they are comparable and no more stringent for MH/SUD services within a classification of benefits than for M/S services within the same classification of benefits.

#### 6. Standards for Provider Credentialing and Contracting

NQTL Type: Network Admissions (Network Adequacy, Credentialing and Provider Reimbursement) – Cigna Administered Plans

Classification(s): Inpatient and Outpatient (In-network)

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

- Provide a clear description of the specific NQTL, plan terms, and policies at issue
- Identify which M/S and MH/SUD benefits are subject to the NQTL

### Step 1 (a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:

Network Admissions is considered a non-quantitative treatment limitation ("NQTL") under the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") and its implementing regulations and sub-regulatory guidance. Network Admissions includes network adequacy, provider credentialing, and provider reimbursement methodologies.

This document represents an NQTL comparative analysis for Network Admissions applied to mental health and/or substance use disorder ("MH/SUD") services, and/or providers of such services, and to medical/ surgical ("M/S") services and/or providers of such services, for inpatient and outpatient benefit classifications and is incorporated into plans insured by Cigna Health and Life Insurance Company ("CHLIC").

Evernorth Behavioral Health ("Evernorth" or "EBH," formerly Cigna Behavioral Health), an affiliate of Cigna Health and Life Insurance Company ("CHLIC"), performs all aspects of provider network admissions including Network Adequacy, Contracting, Credentialing and Reimbursement for the MH/SUD Network, while CHLIC performs all aspects of provider network admissions including Network Adequacy, Contracting, Credentialing and Reimbursement for the M/S Network. References to "Cigna" contained herein include Evernorth Behavioral Health unless otherwise noted separately.

Among the NQTLs applied to MH/SUD and M/S benefits, and for which comparative analyses have been performed, Cigna has assessed several components of its standards for a provider and/or facility (collectively "Network Providers") admission to participate in a network for NQTL compliance, including network adequacy, credentialing and the methodology for determining Network Provider reimbursement rates for inpatient and outpatient services. Cigna does not include specific plan language regarding Network Provider credentialing or Network Provider reimbursement. Wellfleet Claims Data Reimbursement analyzes Provider Specialty Reimbursement vs Medicare rates.

The plan language addressing the Cigna Network, including provider directory is excerpted from representative language incorporated by many plan sponsors into their employee welfare benefit plans, and states as follows. For the purposes of clarity, this analysis excerpts one example of the governing benefit language for brevity.

#### Notice Regarding Provider Directories and Provider Networks

A list of network providers is available to you without charge by visiting the website or by calling the phone number on your ID card. The network consists of providers, including hospitals, of varied specialties as well as general practice, affiliated or contracted with Cigna or an organization contracting on its behalf.

Step 1(b): Identify the M/S benefits/services	Step 1(b): Identify the MH/SUD
for which the NQTL is required:	benefits/services for which the NQTL is
·	required:

All benefits and services are available from the provider network, which is developed through the Network Access strategy.	Same as M/S
Step 2 – Identify the factors used to determine health or substance use disorder benefits and Medical/Surgical:	
Note: although this prompt asks for the "factors used to determine that the NQTL will apply," because this NQTL applies to 100% of benefits in all classifications, this response reflects the factors used in the design of how this NQTL applies to providers of M/S services as compares to providers of MH/SUD services. This is a more meaningful framing for a comparability and stringency analysis for this NQTL type.	Same as M/S
When a medical or behavioral provider requests participation in the Cigna network(s) or when Cigna identifies a provider to recruit into its network(s), the provider is presented with a contract proposal which describes the details of the entire agreement such as obligations of the physician, obligations of Cigna, term of the contract, reimbursement, and applicable state supplemental requirements.  Cigna will respond within 20 days of provider inquiry to join the Cigna network. The provider either accepts the proposed contract or may request negotiated changes to Cigna's standard provider template and standard reimbursement rates. Revisions to the standard Provider contract terms and reimbursement rates are analyzed and negotiated by either a Recruiter or Contract Negotiator, with oversight from a Contracting Director.	
Cigna maintains an open network and will contract with any MH/SUD or M/S provider or facility. Cigna does not limit parties with whom it will contract and negotiate rates. The Behavioral Health medical cost budget and M/S cost budgets are established using	

the same methodology including budgetary considerations for known contractual commitments as well as renegotiation of existing contracts. Additionally new negotiations are reviewed in order to set budget metrics. Cigna does negotiate rates with parties that represent groups or sets of providers. There is no difference in how this process is handled for MH/SUD vs. M/S providers or representatives. When applicable, Ciana uses the same Consultant Agreement for both MH/SUD and M/S. For parties representing groups or sets of providers, Cigna requires each authorized representative to complete and sign a questionnaire and confidentiality agreement in order to participate in contract discussions, contract disputes and/or payment disputes. Based on the questionnaire, answers to these questions will be reviewed by Cigna for a determination of Cigna's willingness to proceed with this representative. This process is followed for both M/S and MH/SUD providers.

#### **Network Adequacy and Credentialing:**

Cigna maintains an open network for both M/S and MH/SUD Network Providers, such that new providers looking to contract with Cigna will be admitted if they meet Cigna's Network Provider admission criteria ("Credentialing Criteria"). Evernorth maintains NCQA Managed Behavioral Healthcare Organization ("MBHO") Accreditation and conducts an annual directory audit which includes a valid random sample to ensure the network and directory meet all NCQA MBHO accreditation requirements. MBHO Accreditation includes standards for Behavioral Health Care, Credentialing/Recredentialing, Provider Accessibility and Availability Monitorina, and Provider Contracting and Satisfaction, Ciana conducts quality management activities for both medical and behavioral healthcare products. Additionally, NCQA performs an

## Network Adequacy and Credentialing:

audit of a random sample of denials, appeals, case management, and credentialing cases (approximately 350 records).

CHLIC also maintains NCQA accreditation, which requires a comprehensive and rigorous audit of the Quality Program documents, policies, and other materials regarding Quality Management, Utilization Management, Case Management, Care Coordination, Credentialing, and Members' Rights & Responsibilities (approximately 250 documents). This evidence spans a period of 2 years and the majority of the evidence has to be reviewed and approved by our Medical Management Quality Committee ("MMQC"), Integrated Health Management Quality Committee ("IHMQC"), and Clinical Advisory Committee ("CAC"). Additionally, NCQA performs an audit of a random sample of denials, appeals, case management, and credentialing cases (approximately 350 records). Ciana maintains one credentialina committee for the review of providers entering the network. Ciana does not routinely track credentialing exceptions for either M/S or MH/SUD Network Providers. Network Providers are re-credentialed on a three-year cycle as required by NCQA. NCQA Accreditation standards require that the organization maintain sufficient numbers and types of behavioral health, primary care and specialty care practitioners in its network. NCQA does not specifically dictate what the appropriate number/type should be. As a result, Cigna conducts review of its Network Adequacy standards at least annually to ensure requirements are sufficient for customer needs. Such analysis reviews external benchmarks (e.g., state laws or CMS requirements) as well as internal review of supply/demand and network adequacy enrollee complaints. Network adequacy analysis considers: geographic area, time/distance standards, provider/enrollee ratio, provider type and/or specialty and supply/demand.

Ciana's Quality Programs and Accreditation team defines quality monitoring standards and provides auidance in initiatina improvement initiatives when deficiencies are identified. Quality studies are designed and documented to objectively and systematically monitor, evaluate and improve the quality and appropriateness of care and service. Monitoring and driving improvements in quality of care and service to our customers is an integral component of Behavioral Accreditation, which reflects the Cigna commitment to continuous quality improvement throughout the organization. For both its M/S provider network and its MH/SUD provider network, Cigna establishes and monitors clinically appropriate: (1) provider to customer ratios by provider type and/or specialty in urban, suburban and rural geographic regions; (2) time/distance standards for accessing the various provider types and/or specialties located within urban, suburban and rural geographic regions; and (3) appointment wait times for emergency care, urgent care and routine outpatient care for the various provider types and/or specialties, as prescribed by NCQA. Assessing supply and demand of M/S and MH/SUD facilities are based upon the same indicators including, but not limited to, NCQA and NAIC network adequacy and access standards focused on distribution of provider types within geographic regions (i.e. zip codes); plan population density within geographic regions (i.e. zip codes); time and/or distance to access provider type within urban, suburban and rural areas; appointment wait times for emergent, urgent and routine visits: customer satisfaction surveys; and customer complaint data. Ratio of Providers to Customers: Providers to customer ratios are normally calculated with the Provider count constant at 1, where the Provider count is based on unique Provider and the Customer count is based on customer's home zip code (students may also provide their school zipcode at the time of enrollment). To convert to a ratio in this

format, Cigna divides the customer count by the Provider count. For example, for an area with 3,000 customers and 30 Providers, – the ratio would be 1:100.

In remote or rural areas, occasionally geographic availability guidelines are not able to be met due to lack of, or absence of, aualified Practitioners and/or Providers. The organization may need to alter the standard based on local availability. Supporting documentation that such situation exists must be supplied along with the proposed guideline changes to the appropriate Quality Committee for approval. Annually, the Quality Management team reviews and assesses the behavioral health care professional network to determine if goals are met and if the network is robust enough to meet the needs of its customers. NCQA requires certain measures to assess availability for urban/suburban, rural, and ratios (behavioral health care professional to customers) across its networks. Likewise, the Network team reviews and assesses the medical health care professional network to determine if goals are met in 90% of the zip codes within the service area for each provider specialty category for PCPs, High Volume Specialist, High Impact Specialists, and Hospitals.

#### Reimbursement:

Cigna's in-network provider reimbursement methodology, exclusive of DRG reimbursement is based upon factors including, but not limited to: geographic market (i.e. market rate and payment type for provider type and/or specialty); type of provider (i.e. hospital, clinic and practitioner) and/or specialty; supply of provider type and/or specialty; supply of provider type and/or specialty; network adequacy and current Medicare reimbursement rates. All staff participating in a contract negotiation are trained on internal Cigna policies and procedures, and have access to necessary tools to negotiate and develop appropriate reimbursement rates based on standard

#### Reimbursement:

methodologies, provider specific reimbursement requests and escalate for justification and approval of any deviations.

Concurrent with the negotiation or immediately thereafter, provider credentialing will be completed by Cigna (or other such delegate of credentialing). The provider must successfully meet Ciana credentialing requirements before the contract may be fully executed. CAQH is utilized to obtain most individual practitioner credentialing related information, expediting the credentialing process while Ciana adhering to all state credentialing review timelines. Upon finalization and successful credentialing, the provider agreement is executed and their participation in the Cigna network(s) begins on the applicable effective date. Specific Factors triggering the application of Network Adequacy standards, credentialing, and reimbursement are detailed below.

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.

Medical/Surgical:	MH/SUD:
Network adequacy:	Network adequacy:
Cigna considers the composition of its	Same as M/S
current medical/surgical network providers	
and MH/SUD network providers by provider	
type and/or specialty, in addition to census	
(membership) data, to ensure it maintains an	
adequate medical/surgical provider network	
and an adequate MH/SUD provider network	

to meet the clinical needs of its customers. Cigna conducts oversight and monitoring of the adequacy of its M/S provider network(s) and MH/SUD provider network to assess whether they are meeting its internal and regulatory driven network access standards. When access to care standards are not met, Cigna engages in active recruitment of the relevant provider type and/or specialty at issue.

Ciana conducts an annual analysis of its network adequacy requirements, and Ciana's medical and behavioral networks meet the company's established access to care standards in urban, suburban, and rural areas. In plans without an out of network benefit, in the event an enrollee cannot secure a provider or appointment within a reasonable time/distance or with reasonable appointment availability Evernorth Behavioral Health ("EBH") will authorize out-of-network services at the in-network benefit level. Enrollees are able to receive assistance in locating a provider or appointment by contacting the phone number on the back of their ID card. In the event the enrollee and/or a Cigna representative cannot locate a provider/appointment within the acceptable time/distance standards a request can be made for out-of-network care at the in-network benefit level for plans without out of network benefits. As an additional way of ensuring meaningful access to services, Ciana also measures, consistent with NCQA standards, accessibility of care to MH/SUD providers annually using findings from enrollee surveys and complaints and by measuring results against the accessibility standards and metrics. Ciana uses the continuous quality improvement (CQI) process to identify opportunities for improvement. Cigna has reviewed and rendered uniform, where appropriate, its M/S and MH/SUD network adequacy policies and procedures to ensure comparability across M/S and MH/SUD providers. These policies and procedures are reviewed at least annually to ensure the continued sufficiency

of the standards in meeting enrollees' needs. Cigna uses a combined network adequacy policy and a similar reporting template is used for both M/S and MH/SUD benefits.	
Credentialing: Credentialing criteria for both M/S and MH/SUD Network Providers includes the following standard requirements: (1) signed agreement to participate (2) signed application and provider attestation (3) verification of unrestricted state medical license with appropriate licensing agency; (4) verification of valid, unrestricted DEA certificate (if applicable); (5) verification of full, unrestricted admitting privileges at a Cigna participating hospital; (6) verification Board certification, (if applicable); (7) verification of highest level of education and training, if not board certified; (8) review and verification of malpractice claims history; (9) review of work history; (10) verification of adequate malpractice insurance; and (11) verification of prior and current sanction activities Additional criteria may be applicable pursuant to state credentialing and licensing requirements.	Credentialing:
Reimbursement: Whether for initial negotiation or renegotiation, Cigna's Network Provider reimbursement methodology for MH/SUD and M/S Network Providers are based upon the same array of factors. Re-negotiations of reimbursement rates are conducted according to the terms of the contract, or if not specified in the contract, they are conducted at the request of either party. The number of Network Providers (Individual, Group or Facility) joining or already part of the network does not factor into initial rate offerings. M/S and MH/SUD facilities may be reimbursed per diem, Diagnosis Related Group or case rate. Per diem reimbursement involves a flat dollar amount for each day as reimbursement for the service. DRG	Reimbursement:

reimbursement is based upon Medicare DRG calculations, which assign payment levels to each DRG based on the average cost of treatment. Case rates, also referred to as flat rates, describe a reimbursement structure in which providers receive a flat reimbursement rate for every patient visit, regardless of the service (most often utilized in urgent care). Cigna does not determine or mandate the reimbursement type: selection of reimbursement type is determined by the facility. Generally, M/S facility providers request DRG reimbursement, while MH/SUD facility providers request per diem reimbursement. More than 90% of MH/SUD Provider Network contracts reflect per diem reimbursement. The evidentiary factors taken into consideration in the negotiation of the per-diem rate are not weighted or prioritized one more than the other; however, additional consideration may be given to meet network adequacy standards.

Factors for reimbursement negotiation include: (1) Geographic market, which may be adjusted based upon Medicare Geographical Practice Cost Index ("GPCI") Geographic Practice Cost Index (GPCI) reflects the relative cost of practicing in a locality against a national average. Each relative value is multiplied by the corresponding GPCI. The three component factors are then accumulated to arrive at an adjusted amount. This amount is then multiplied by the conversion factor to establish the Medicare full fee schedule amount in the Medicare Physician Fee Schedule Data Base (MPFSDB). CMS performs calculations on the fee schedule, with the exception of carrier-priced procedure codes, and provides fee schedule calculations to the Medicare Administrative Contractors (MACs). Geographic Practice Cost Index is not weighted for purposes of per diem

reimbursement; (2) Type of provider and/or specialty (e.g. physician practitioner v. nonphysician practitioner v. facility); Provider types are dependent upon state licensing and credentialing requirements as outlined by the applicable state or NCQA. Cigna does not weight provider types or designate any additional provider and/or specialty designations (e.g. physician practitioner v. non-physician practitioner); (3) Supply of provider type and/or specialty. Provider specific fee schedules are used for multispecialty specialty groups or unique specialty groups where reimbursement terms must be customized to meet the needs of that group or specialty. Provider specific or specialty fee schedules are used to retain providers if the providers are needed to meet network access requirements and/or increase membership. Supply of provider type and/or specialty are not weighted in relation to the other evidentiary standards for purposes of per diem reimbursement; (4) Network need and/or demand for provider type and/or specialty. Network need and/or demand for provider type or specialty is defined by state adequacy requirements. Cigna contracts with practitioners and providers across all networks and for all product lines to meet the availability and cultural needs and preferences of customers, establishes availability standards and assesses its networks against those standards articulated in Cigna's Measuring Availability of Practitioners and Providers Policy. Need and/or demand for provider type and/or specialty are not weighted in relation to the other evidentiary standards for purposes of per diem reimbursement; (5) Training, experience and licensure of providers billing for professional services under the facility agreement. Training, experience and licensure of providers billing for professional services under the facility agreement are not

specifically weighted in relation to the other evidentiary standards for purposes of per diem reimbursement; (6) Medicare reimbursement rates for codes with assigned Medicare Relative Value Unit ("RVU"). RVUs are the basis of the RBRVS system. Unit values are assigned to each service (CPT code) by area of specialty and for some codes, different RVUs for site of service: facility and non-facility. RVUs are not weighted for per diem reimbursement;

Cigna utilizes the Medicare Pricing Tool to determine if the provider's (current) rates are above the defined Medicare Baselines. The minimum standards are designated as a percentage of Medicare reimbursement, according to licensure and Medicare locality. Cigna uses standard Medicare Resource Based Relative Value Scale ("RBRVS"), a CMS created reimbursement methodology to reimburse providers for members covered under the Medicare program and as a baseline for commercial reimbursement rates. Cigna's RBRVS methodology calculates the allowable fee for a covered service. Ciana RBRVS is set annually:

[(Work RVU x Work GPCI) + (Practice RVU x Practice GPCI) +

(Malpractice RVU x Malpractice GPCI)] x Conversion Factor = Reimbursement

RVUs are the basis of the RBRVS system. Unit values are assigned to each service (CPT code) by area of specialty and for some codes, different RVUs for site of service: facility and non-facility. Three components are used to make up a total RVU (1) Physician's work – This component accounts for the providers time, technical skill, mental effort, and physiological stress; (2) Practice

expense – This component includes office rent, wages, supplies, equipment; (3) Malpractice Expense - This component includes professional liability insurance cost. To fill gaps for codes not covered by RBRVS methodology Cigna uses relative values assigned by Optum (Ingenix) for M/S services. Optum (Ingenix), is a third party health data company, that uses the same methodology originally used to develop the values for Medicare covered services. For those services that cannot be valued using a resource-based methodology, values have been developed using alternative methodologies proprietary to Optum (Ingenix). In an RBRVS calculation, each component of an RVU is multiplied by its GPCI then totaled and multiplied by the conversion factor to determine the fee or payment. Cigna uses the same GPCIs as Medicare. There are approximately 89 GPCIs. Cigna uses Optum (Ingenix) values to fill gaps for codes not covered by RBRVS methodology.

Facility rate categories are industry standard with the market and economy dictating rates for both M/S and MH/SUD facilities. Cigna utilizes Medicare's resource-based relative value scale (RBRVS) calculation (OP-BH & Med). This calculation is premised on the principle that payments for services should vary with the resource cost for providing the services. In each instance, the fee schedule is separately reviewed and negotiated.

For DRG reimbursement, weighting is not calculated within the contract or at the time of contract rate negotiation, but instead occurs at the time of payment as DRG reimbursement is dependent on a variety of variable factors such as patient age and diagnosis. When behavioral contracts at a per diem rate, the population and type of

care are distinguished in the contract and rates are negotiated separately. Cigna utilizes CMS grouping software (Optum) that takes the information from the claim and "groups it" into the correct DRG. Then that DRG information is used to calculate the reimbursement, based on the factor in the contract; by way of example: DRG 203 has a factor 17; CMS DRG weight x contracted factor = reimbursement.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.

In writing Analysis:

Network Adequacy:
Both MH/SUD and M/S negotiations are based upon provider and information availability at a single point in-time. Network adequacy standards (Network Need) is a contributing factor for both MH/SUD and M/S providers during a reimbursement negotiation. It is important to note that different providers and facilities have vastly different negotiating or so-called bargaining

power. A provider's bargaining power depends on several factors of which cannot simply be reduced to supply and demand including the provider's size (e.g., a large statewide or national hospital system vs. an individual solo practitioner); the scarcity or the "supply" of that provider type or specialty; and the reputation, name recognition, and/or quality of the provider. As expected, providers and facilities that for a variety of reasons have more bargaining power are able to negotiate higher reimbursement. Ciana measures accessibility of care to behavioral (prescriber and nonprescriber), PCP, and High-Impact/High-Volume SPC providers using findings from customer surveys and complaints, and by measuring results against the accessibility standards and metrics annually. Ciana uses the continuous quality improvement ("CQI") process to identify opportunities for improvement and when network adequacy gaps are identified and brought to the attention of the Behavioral Health Provider Operations Program Management Team (for either provider or facility). That team researches available providers and prioritizes recruitment efforts. The recruitment timeline is as follows:

If Ciana identifies a network adequacy deficiency, it attempts to remediate the deficiency. The identified potential provider may decline participation in the network or may not respond to recruitment efforts. If Cigna identifies a non-contracted provider needed for adequacy/accessibility, it may offer higher rates than what would otherwise be standard in order to close the gap. NCQA does not prescribe goals for geo access. Cigna uses a 90% standard, which aligns with CMS network adequacy requirements, which require that 90% of customers have access to providers based on network adequacy access requirements for time and distance standards. Cigna monitors network adequacy on at least an annual basis and creates recruitment and corrective action plans to

address any deficiencies. In many instances, deficiencies are a result of insufficient availability of providers/facilities. Both MH/SUD and M/S networks are held to the same 90% standard. In most instances inability to meet the 90% threshold is related to insufficient provider availability. Lack of providers/facilities tends to impact behavioral more than medical. Ciana actively recruits providers in areas where there may be access deficiencies. In some cases, not enough providers exist in a given geographic area and thus Ciana cannot meet a network adequacy standard due to provider unavailability. In such situations, Cigna takes steps to ensure that an enrollee in a plan using this network would be able to receive medically necessary services from an out of network provider, and the services would be treated as in-network for purposes of cost-sharing or other requirements.

#### **Credentialing:**

Cigna's methodology for credentialing for M/S and MH/SUD physician providers are the same. Cigna credentialing standards for licensed physicians follows NCQA, CMS, state and federal requirements and guidelines for each provider and/or specialty type. Cigna does not maintain separate standards for MH/SUD providers. Moreover, the standard credentialing process is used for both licensed physician providers and licensed non-physician providers, whether they are M/S or MH/SUD providers. Re-credentialing is required every three years for all providers. and except for work history and education and training verification, requires providers to meet the same criteria as the initial credentialing process, unless a new specialty is being requested.

The credentialing application process is consistent between physicians and facilities providing M/S and MH/SUD services and the required licensing, experience, CAQH application and verifications are indistinguishable. No additional Cignaspecific credentialing requirements are

#### **Credentialing:**

applied to either M/S or MH/SUD physician providers, and, as relevant for certain MH/SUD services or specialties, Cigna does not require that MH/SUD practitioners or facilities be licensed or accredited if such a license or accreditation would not be required by state law. Consistency in credentialing standards and process evidences compliance with the NQTL inwriting requirement.

#### **Provider Reimbursement**

Whether for initial negotiation or renegotiation, Ciana uses its standard innetwork provider reimbursement methodology for MH/SUD and M/S providers. Network adequacy deficiencies (Network Need) is always considered when negotiating reimbursement rates. Standard reimbursement rates for inpatient and outpatient services for both M/S and MH/SUD providers are set based upon standard fee schedules, which are developed for facilities, physicians and non-physicians by state or region and reflect geographic variations within that state or region. Provider-specific fee schedules are developed based upon the professional or facility's negotiation request or business need, including the satisfaction of network adequacy requirements. Cigna's preferred standard is to reimburse the same rates across all plans/products. M/S contracts have the option to pay plans differently, while BH pays the same for all plans. This approach provides more favorable rates for MH/SUD providers. For example, BH pays the same rate for a Medicare provider as it does for a commercial provider. Rates may be negotiated differently depending upon plan if requested.

In determining any rate in both the M/S and MH/SUD facility agreements, Cigna assesses supply and demand of provider types and/or specialties based upon the same indicators including, but not limited to NCQA network adequacy and access standards focused on distribution of provider types within geographic regions (i.e. zip codes); plan

#### **Provider Reimbursement**

population density within aeographic regions (i.e. zip codes); time and/or distance to access provider type within urban, suburban and rural areas; appointment wait times for emergent, urgent and routine visits; customer satisfaction surveys; and customer complaint data. That is, Cigna's reimbursement rate development and negotiation processes are ultimately designed to ensure achievement of its adequacy standards for MH/SUD and M/S providers, and any departure from the standard fee schedules is informed by market demand, which may include, for example, the need to maintain, or achieve, network adequacy for a provider type in a particular geographic area.

Facility Reimbursement – Inpatient In-network facility-based services which are not reimbursed on an assigned diagnosisrelated group (DRG) or case rate basis may generally be reimbursed on a per diem or discount basis. Currently, M/S has many more DRG contracts while a small minority of MH/SUD contracts are paid as DRG or case rate. Specifically, M/S paid just under 60% of admissions last year under DRGs and 20% as per-diem, and 20% as a percent of charges. MH/SUD are essentially 100% per-diem, as MH/SUD contracts do not have any significant case rates or percent of charges contracts. DRG (i.e. case rate) reimbursement rates generally do not exist for MH/SUD in-network inpatient services because unlike certain routine medical inpatient procedures (i.e. vaginal deliveries; cesarean deliveries; appendectomies, etc.), MH/SUD inpatient stays vary depending upon the unique clinical needs, circumstances and complexities of the individual patient (i.e. patient's insight or lack of insight into their illness; patient motivation to receive treatment; comorbidity, etc. Per diem reimbursement for both M/S and MH/SUD facility-based services are based upon the following factors and accompanying evidentiary standards: (1) geographic market, which may be adjusted

based upon Medicare Geographical

Practice Cost Index ("GPCI"); (2) type of provider and/or specialty (e.g. physician practitioner v. non-physician practitioner v. facility); (3) supply of provider type and/or specialty; (4) network need and/or demand for provider type and/or specialty; (5) Medicare reimbursement rates for codes with assigned Medicare Relative Value Unit ("RVU"); and (6) Training, experience and licensure of providers billing for professional services under the facility agreement. Cigna's methodology and process for negotiating in-network provider reimbursements for M/S and MH/SUD services within a classification of benefits are comparable and no more stringent for MH/SUD services than for M/S services within the same classification of benefits as written. Ciana also follows a comparable process in determining payment rates for non-physician providers for both M/S and MH/SUD benefits. While there is variation in type of reimbursement methodology for facility reimbursement, Ciana's Network Providers choose which methodology (DRG, Per Diem or Case Rate) will apply and the processes. factors and evidentiary standards applicable to each methodology is applied to M/S and MH/SUD providers consistently. In this process, variables including market demand, provider specialty and availability and frequency of requests for provider fee increases may result in differentials in reimbursement rates across medical/suraical and MH/SUD provider types.

#### In Operation Analysis

## In operation – data M/S:

This comparative analysis was drafted based on Cigna Credentialing and Network Access Reporting provided below.

### In operation – data MH/SUD:

This comparative analysis was drafted based on Cigna Credentialing and Network Access Reporting provided below.

Metric	Medical
Time/Distance Report	PCP = 100% (met) Specialist = 98% - 100% (met)
Provider/Enroll ee Ratio	PCP Ratio (1 PCP: 300 Members): Met Specialist Ratio except ophthamology and OBGYN (1 Spec: 10,000 Members): Met Specialist Ratio ophthamology and OBGYN Specialist Ratio (1 Spec: 2,000 Members): Met

Credentialing	Medical	%
Total number of		
requests	55631	
Total approved	55447	99.67%
Total denied	184	0.33%
Total number of		
denials		
appealed	24	13%
Number of		
appeals		
overturned	9	38%
Number of		
appeals upheld	15	62.5%
List Top 5	1.	
Credentialing	Malpractice	
Denial Reasons	Issue	
	2. License	
	Issue	
	3. Board	
	Certification	
	Issue	
	4. Hospital	
	Privileges	
	5.	
	Govt/Federa	
	I Business	
	Excl	

Metric	Behavioral
Time/Distance Report	Master's Level Clinician: 97% (met) Psychologist: 83% (not met) Physician 90% (met)
Provider/Enroll ee Ratio	Masters Ratio (1 Masters Level Clinician: 800 Members): Met Psychologist Ratio (1 Psychologist: 1,500 Members): Met Prescriber Ratio (1 Psychiatrist/NP: 1,500 Members): Met Inpatient Facility Ratio (1 Facility: 10,000 Members): Met Residential Facility Ratio (1 Facility: 20,000 Members): Met Ambulatory Program Ratio (1 Program: 10,000 Members): Met

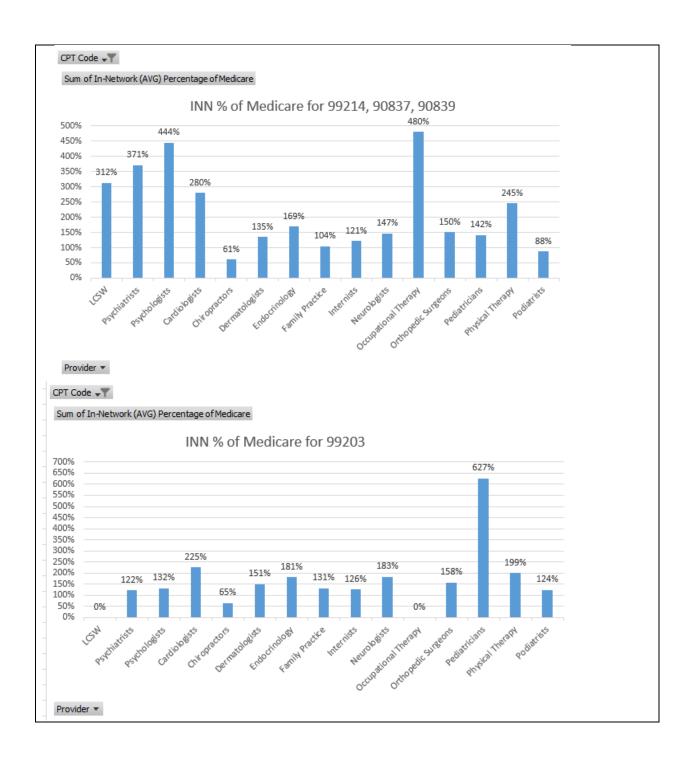
Credentialin	Behavioral	
g		%
Total number		
of requests	45271	
Total		99.87
approved	45211	%
Total denied	60	0.13%
Total number		
of denials		
appealed	2	0.03%
Number of		
appeals		
overturned	1	0.17%

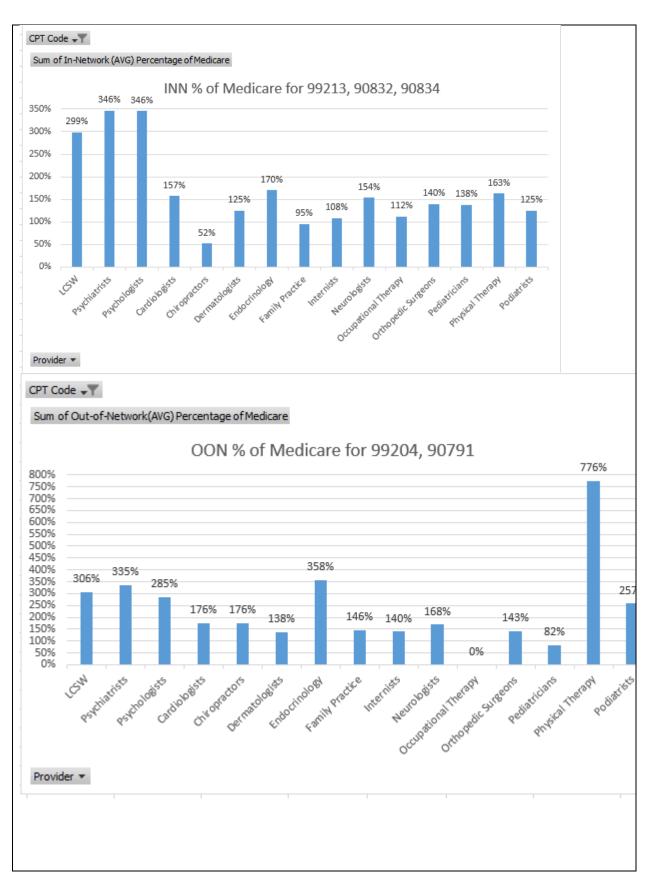
Average credentialing		Number of appeals		
approval TAT	25.24 days	upheld	1	0.17%
Average		List Top 5	1. License	
credentialing		Credentialin	Issue	
denial TAT	87.66 days	g Denial	2.	
		Reasons	Malpractic	
			e Issue	
		Average		
		credentialing		
		approval TAT	21.95 days	
		Average		
		credentialing		
		denial TAT	87.86 days	

#### WELLFLEET

Wellfleet performed a comparison of average out of network claims payments during calendar year 2023 as a percentage of Medicare rates for the Wellfleet book of business for nine (9) CPT codes across three (3) MedSurg primary care physician types, five (5) MedSurg physician specialty types, four (4) MedSurg ancillary types and, one (1) MHSUD physician type, and two (2) MHSUD ancillary types. The results are as follows:

- 99203: There were insufficient MH/SUD 99203 claims except for psychologists resulting on 373% more than Medicare, whereas the MedSurg claims for 99203 were from 114% to 241% of Medicare. No concerning differences were noted.
- 99213, 90832 & 90834: MH/SUD psychiatrists, social workers and psychologists were reimbursed the most (> 500% of Medicare) vs. MedSurg PCPs (120-188% of Medicare) vs. MedSurg specialists (87%-311% of Medicare). The significant results for both M/S and MH/SUD show reimbursement substantially more for MHSUD.
- 99204 & 90791: MedSurg shows significant outlier of Physical Therapy at 776% of Medicare whereas the rest of MedSurg shows average of 140-358% of Medicare. MH/SUD significant results were both reimbursed >285% of Medicare. No concerning differences were noted.
- 99214, 90837 & 90830: MHSUD claims show a significant % of Medicare reimbursed more than that of MedSurg providers.





#### In operation – comparative analysis:

**Network adequacy:** A review of Ciana's Network Adequacy reports for Ciana's national network revealed sufficient access to M/S and MH/SUD providers. Ciana meets adequacy and accessibility requirements for M/S and MH/SUD providers using comparable standards, with M/S providers subject to more stringent standards. At present, Cigna meets all provider ratio access requirements for Masters Level Clinicians, Psychologist/Nurse Practitioners with prescribing privileges, Physicians, Inpatient Facility and Residential Facility for the MH/SUD Network. Cigna also meets all provider ratio access requirements for adult and pediatric PCP; high volume specialty including cardiology, dermatology, ophthalmology, and orthopedics; and high impact specialty for hematology/oncology, infectious disease, nephrology, neurology and pulmonary. Holistically, when reviewing the current snapshot of both the M/S and MH/SUD networks, Cigna also meets provider access radius requirements. When reviewed individually by state, deficiencies are noted in rural areas such as Alaska, Idaho, Montana, South Dakota and Wyoming in both the M/S and MH/SUD Networks. Lastly, Cigna reviewed the percentages of exceptions for obtaining out-of-network M/S and MH/SUD services at the in-network benefit level to ensure operational parity compliance. Data revealed a significantly larger number of M/S network exceptions denied including both medical necessity and administrative denials than denials of MH/SUD network exceptions.

**Credentialing:** An "in operation" review of Cigna's credentialing applications, approvals and denials of providers revealed no disparate outcomes in credentialing approvals or denials as between M/S and MH/SUD physician providers. The average time it took Cigna to review and approve a credentialing application for both M/S and MH/SUD providers was 23.6 days, a 25 day approval average for M/S providers and a shorter 22 day approval average for MH/SUD providers. The average time it took Cigna to review and deny a credentialing application for both M/S and MH/SUD providers was 87 days. These credentialing process metrics indicate a comparable process in-operation based on the time to review, a significantly lower amount of denials of MH/SUD provider credentialing applications, and comparable incidences of denials of MH/SUD and M/S provider credentialing denial overturns on appeal. Consequently, Cigna concludes that the NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

#### Reimbursement:

#### Wellfleet

In terms of operational parity compliance, Wellfleet has assessed the reimbursement rates paid across its book-of-business by reference to reimbursement data in 2023. In its assessment, Wellfleet reviewed CPT codes for ancillary, PCP, and specialists for MHSUD & MedSurg. Wellfleet has determined that the reimbursement rates are comparable and not more stringent once Wellfleet eliminates the high outlier claims for ancillary therapy provider types. By contrast, MH/SUD providers are reimbursed at

a higher or comparable average for CPT codes 99203, 99213, 99214, 90832, 90834, 90837, & 90839, compared to M/S providers.

The analysis of the 2023 claims reimbursement demonstrates the payment versus Medicare rates for the same provider types and CPT codes did not provide concerns regarding possible issues with disparities in payment between similar types of MH/SUD versus MedSurg providers. Moreover, as demonstrated by the bar graphs, the reimbursement rates as a percentage of Medicare for MH/SUD providers are comparable or higher than the reimbursement rates as a percentage of Medicare for MedSura providers, apart from therapists, who are a significant outlier for specified code groups for both in-network and out-of-network reimbursement. Therefore, in operation, the processes, standards, factors, and sources used to apply reimbursement to MH/SUD services is comparable and not more stringent than the processes, standards, factors, and sources used to apply reimbursement to MedSurg services. Wellfleet concludes that it applies reimbursement either equally or less stringently for MH/SUD providers than it does for MedSurg providers. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement.

#### Cigna

In December 2021, Cigna conducted a comparison of DRG reimbursement to innetwork M/S facilities compared to per diem used for MH/SUD in-network facility-based services. To conduct the comparative analysis of in-network facility reimbursement by DRG payment system methodology versus per diem payment methodology, Cigna did not target a specific facility's DRGs, but rather claim line data aligning a DRG to a diagnostic code only. The top 35 diagnostic codes were obtained from the dataset through a group by statement ordered descending to identify the 35 diagnostic codes with the highest allowed spend for the time period of the analysis; FY2020. An average allowed amount was derived at the diagnostic code level for a comparison of Avg. Per Day, Avg. Per Unit, and Avg. Per Member from claim line data designated as Behavioral compared to claim line date designated as Medical. The analysis was not inclusive of expected lengths of stay.

Cigna reviewed the DRGs for M/S admissions to determine the "daily" rate average for inpatient admission based on the expected length of the DRG. To unpack the DRG rate, Cigna applied this back to the length of stay that is contemplated by the respective DRGs, as they are different for every diagnosis. Once the DRG daily rate was determined, Cigna compared it to the MH/SUD reimbursement for a hospital bed day. Specifically for the comparison, Cigna utilized the most comparable lists of admission diagnoses between M/S and MH/SUD services which included the top 35 inpatient diagnosis codes. Cigna's data warehouse cross-walked claims using logic to identify MH/SUD spend apart from M/S spend so like services would not be included in the comparison when reviewing by diagnosis. This logic ensured a singular classification. For example: Primary diagnosis of F329 for Behavioral may align to an Inpatient admission with a bed day per diem, and the same diagnosis for Medical may align to an ER Level 1 case rate. Given the vast differences between M/S and MH/SUD inpatient stays and variation of diagnoses, singular classifications were omitted. Cigna's MH/SUD network does not provide separate reimbursements for

different plans, so the reimbursement diagnosis codes and average units were based on Cigna's commercial book of business. Inpatient admissions included all of the MH/SUD IP levels of care: Inpatient Behavioral Health Level of Care, Adult, Inpatient Behavioral Health Level of Care, Child or Adolescent, Eating Disorders, Inpatient Behavioral Health Level of Care, Adult and inpatient substance use disorder treatment level of care and inpatient detox level of care Substance Use Disorder inpatient levels of care which included ASAM Level 4 and ASAM Level 3.7.

The facility reimbursement comparative analysis reflects that, on average, Cigna applied a 54.6% discount for MH/SUD services and 50.6% discount for M/S services resulting in a 4% spread between the two, which can be categorized as comparable and not resulting in a disparate outcome. The direct DRG/Per Diem comparison resulted in a difference of \$7,133 average per day difference between M/S and MH/SUD inpatient stays, in favor of the MH/SUD per diem stay receiving higher reimbursement.

While the comparison of two distinct methodologies is inherently challenging due to the material differences in how facility-based services are reimbursed and the DRG-Per Diem comparison evidences a difference in the MH/SUD and M/S reimbursement rates, this does not indicate a disadvantageously disparate outcome for inpatient stays. In fact, in this instance the comparison illustrates a higher average per unit and per day cost for MH/SUD per diem facilities than M/S facilities paid the DRG rate. As a general matter, due to variability in length of stay for MH/SUD benefits per diem reimbursements are more favorable for MH/SUD than are DRGs. In other words, if Cigna sought to impose DRGs on MH/SUD benefits it would likely reduce reimbursement rates because the course of treatment is relatively unpredictable for MH/SUD conditions as opposed to M/S conditions. This presupposition aligns with the fact that MH/SUD facilities have rejected DRG reimbursement. It can be assumed a lower reimbursement rate could impact accessibility to in-network providers and Ciana's network admissions criteria, itself the relevant NQTL. However the DRG-Per Diem comparison coupled with Cigna's comparable out-of-network utilization over the recent measurement period across MH/SUD and M/S benefits and the achievement of applicable network adequacy requirements for MH/SUD and M/S providers, respectively, evidences comparability.

# Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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

Cigna assesses supply and demand of both M/S and MH/SUD provider types and/or specialties based upon the same indicators including NCQA and NAIC, and federal/state, network adequacy and access standards focused on distribution of provider types within geographic regions (i.e. zip codes); plan population density within geographic regions (i.e. zip codes); time and/or distance to access provider type within urban, suburban and rural areas; appointment wait times for emergent,

urgent and routine visits; customer satisfaction surveys; customer complaint data. The conclusion of such assessments may result in an increase or decrease in the provider's reimbursement rate.

Over the past several years Cigna has conducted a comprehensive review of its MH/SUD network admission standards, including network access standards, contracting processes and reimbursement rates applicable to Network Providers. Any variances in contracting processes as well as a range of reimbursement rates based on percentages of Medicare RVUs as compared to M/S reimbursement rates were identified and analyzed for adherence to the NQTL requirement. In connection with its ongoing NQTL compliance efforts, Cigna has taken proactive, additional steps to continually ensure the comparability of standards for provider admissions into the MH/SUD provider network, including reimbursement rate methodology, to ensure the processes, strategies and evidentiary standards implemented are not more stringent for MH/SUD services than M/S services. First, Cigna has aligned contracting policies and processes and rolled out a facility reimbursement strategy shifting from reactively addressing disparate outcomes between M/S and MH/SUD reimbursement rates to proactively updating reimbursement rates for facilities for which rate increases have not been requested in the past two years. As evidence of Cigna's success in establishing rates that help ensure the acquisition and retention of providers in its MH/SUD network, the facility rate renegotiation report for January 1, 2020 through March 31, 2021 documented 487 provider renegotiations, of which 446 negotiations were completed, 11 are currently in process and 31 were discontinued due to provider's non-responsiveness, 2 discontinued due to a Special Investigations audit, and 1 was discontinued due to the facility requesting fees for services for which they lacked a state-required license. Ciana has also reviewed more than 10.000 reimbursement rates for outpatient based fee schedules. The outpatient rate negotiation report for January 1, 2020 through March 31, 2021 includes a total of 10,559 rate increases with 9,497 completed and 933 were denied or incomplete due to the non-responsiveness of the provider. Network adequacy standards for MH/SUD providers are comparable to similar M/S specialists. In most instances the behavioral network adequacy standards require a customer to travel fewer miles to see a MS/SUD specialist as compared to an M/S specialist, effectively making MH/SUD providers more accessible to customers as compared to medical specialists. Currently, for both M/S and MH/SUD providers, at least 90% of enrollees are required to have the designated access to meet Cigna's network adequacy standard.

In addition to rolling out reimbursement upgrades for so-called stagnant contracts (that is, facility contracts that have not requested an increase in rates within the past 5 years and have remained at the same percentage of Medicare), facility based reimbursement is transitioning from a service level approach of negotiation to a total cost of care to address both competitiveness through the use of pricing benchmarks and market based analysis. This approach aligns with the methodology and process for updating inpatient reimbursement rates for hospitals providing M/S services. Cigna is currently creating a database including various benchmarking sources for the comparison of in-network rates against pricing benchmarks to assess affordability and to ensure the closure of any unsubstantiated gaps in reimbursement rates. Lastly, for new providers entering the network, Cigna has aligned the contracting process and has developed and implemented a standard reimbursement methodology for

the negotiation of MH/SUD reimbursement rates with M/S contracting and reimbursement methodology. Such alignment includes the implementation of standard fee schedules and the implementation of established outpatient facility and practitioner fee schedules and exceptions to standard fee schedule requests in order to contract with and retain providers essential to the integrity of the MH/SUD provider network.

An analysis of Wellfleet's in-network payments versus Medicare rates for the same provider types and CPT codes did not provide concerns regarding possible issues with disparities in payment between similar types of MH/SUD versus M/S providers. Moreover, as demonstrated by the bar graphs in Step 4, the INN reimbursement rates as a percentage of Medicare for MH/SUD providers is comparable to the OON reimbursement rates as a percentage of Medicare for M/S providers, with the exception of therapists, who are a significant outlier for specified code groups for both in-network and out-of-network reimbursement. Therefore, in operation, the processes, standards, factors, and sources used to apply OON reimbursement to MH/SUD services is comparable and not more stringent than the processes, standards, factors, and sources used to apply OON reimbursement to M/S services. Wellfleet concludes that it applies reimbursement either equally or less stringently for MH/SUD providers than it does for M/S providers.

Consistent with the NQTL requirement for comparability/stringency, Cigna has confirmed that standards for provider admission into the MH/SUD provider network, including credentialing, adequacy, and provider reimbursement rates for inpatient and outpatient services are comparable to, and applied no more stringently than, that of the M/S provider network as written and in operation. Put differently, Cigna's network has the ability to meet the MH/SUD services needs of our enrollees by providing reasonable access to a sufficient number of in-network providers for both inpatient and outpatient services.

- 7. Exclusions for Failure to Complete a Course of Treatment
- 8. Restrictions that Limit Duration or Scope of Benefits for Services
- 9. Restrictions for Provider Specialty

NQTL Type: Network Admissions (Network Adequacy, Credentialing and Provider Reimbursement) – Cigna Administered Plans

Classification(s): Inpatient and Outpatient (In-network)

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

 Provide a clear description of the specific NQTL, plan terms, and policies at issue Identify which M/S and MH/SUD benefits are subject to the NQTL

## Step 1(a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:

Network Admissions is considered a non-quantitative treatment limitation ("NQTL") under the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") and its implementing regulations and sub-regulatory guidance. Network Admissions includes network adequacy, provider credentialing, and provider reimbursement methodologies.

This document represents an NQTL comparative analysis for Network Admissions applied to mental health and/or substance use disorder ("MH/SUD") services, and/or providers of such services, and to medical/ surgical ("M/S") services and/or providers of such services, for inpatient and outpatient benefit classifications and is incorporated into plans insured by Cigna Health and Life Insurance Company ("CHLIC").

Evernorth Behavioral Health ("Evernorth" or "EBH," formerly Cigna Behavioral Health), an affiliate of Cigna Health and Life Insurance Company ("CHLIC"), performs all aspects of provider network admissions including Network Adequacy, Contracting, Credentialing and Reimbursement for the MH/SUD Network, while CHLIC performs all aspects of provider network admissions including Network Adequacy, Contracting, Credentialing and Reimbursement for the M/S Network. References to "Cigna" contained herein include Evernorth Behavioral Health unless otherwise noted separately.

Among the NQTLs applied to MH/SUD and M/S benefits, and for which comparative analyses have been performed, Cigna has assessed several components of its standards for a provider and/or facility (collectively "Network Providers") admission to participate in a network for NQTL compliance, including network adequacy, credentialing and the methodology for determining Network Provider reimbursement rates for inpatient and outpatient services. Cigna does not include specific plan language regarding Network Provider credentialing or Network Provider reimbursement. Wellfleet Claims Data Reimbursement analyzes Provider Specialty Reimbursement vs Medicare rates.

The plan language addressing the Cigna Network, including provider directory is excerpted from representative language incorporated by many plan sponsors into their employee welfare benefit plans, and states as follows. For the purposes of clarity, this analysis excerpts one example of the governing benefit language for brevity.

#### Notice Regarding Provider Directories and Provider Networks

A list of network providers is available to you without charge by visiting the website or by calling the phone number on your ID card. The network consists of providers,

including hospitals, of varied specialties as well as general practice, affiliated or contracted with Cigna or an organization contracting on its behalf.

## Step 1(b): Identify the M/S benefits/services for which the NQTL is required:

All benefits and services are available from the provider network, which is developed through the Network Access strategy.

## Step 1(b): Identify the MH/SUD benefits/services for which the NQTL is required:

Same as M/S

Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits

Medical/Surgical:	MH/SUD:
Note: although this prompt asks for the "factors used to determine that the NQTL will apply," because this NQTL applies to 100% of benefits in all classifications, this response reflects the factors used in the design of how this NQTL applies to providers of M/S services as compares to providers of MH/SUD services. This is a more meaningful framing for a comparability and stringency analysis for this NQTL type.	Same as M/S
When a medical or behavioral provider requests participation in the Cigna network(s) or when Cigna identifies a provider to recruit into its network(s), the provider is presented with a contract proposal which describes the details of the entire agreement such as obligations of the physician, obligations of Cigna, term of the contract, reimbursement, and applicable state supplemental requirements.	
Cigna will respond within 20 days of provider inquiry to join the Cigna network. The provider either accepts the proposed contract or may request negotiated	

changes to Cigna's standard provider template and standard reimbursement rates. Revisions to the standard Provider contract terms and reimbursement rates are analyzed and negotiated by either a Recruiter or Contract Negotiator, with oversight from a Contracting Director.

Ciana maintains an open network and will contract with any MH/SUD or M/S provider or facility. Cigna does not limit parties with whom it will contract and negotiate rates. The Behavioral Health medical cost budget and M/S cost budgets are established using the same methodology including budgetary considerations for known contractual commitments as well as renegotiation of existing contracts. Additionally new negotiations are reviewed in order to set budget metrics. Cigna does negotiate rates with parties that represent groups or sets of providers. There is no difference in how this process is handled for MH/SUD vs. M/S providers or representatives. When applicable, Cigna uses the same Consultant Agreement for both MH/SUD and M/S.

For parties representing groups or sets of providers, Cigna requires each authorized representative to complete and sign a questionnaire and confidentiality agreement in order to participate in contract discussions, contract disputes and/or payment disputes. Based on the questionnaire, answers to these questions will be reviewed by Cigna for a determination of Cigna's willingness to proceed with this representative. This process is followed for both M/S and MH/SUD providers.

#### **Network Adequacy and Credentialing:**

Cigna maintains an open network for both M/S and MH/SUD Network Providers, such that new providers looking to contract with Cigna will be admitted if they meet Cigna's Network Provider admission criteria ("Credentialing Criteria"). Evernorth maintains NCQA Managed Behavioral Healthcare Organization ("MBHO") Accreditation and conducts an annual directory audit which includes a valid random sample to ensure the network and directory meet all NCQA MBHO accreditation requirements. MBHO Accreditation includes standards for Behavioral Health Care, Credentialing/Re-credentialing, Provider Accessibility and Availability Monitoring, and Provider Contracting and Satisfaction. Cigna conducts quality management activities for both medical and behavioral healthcare products. Additionally, NCQA performs an audit of a random sample of denials, appeals, case management, and credentialing cases (approximately 350 records).

CHLIC also maintains NCQA accreditation, which requires a comprehensive and rigorous audit of the Quality Program documents, policies, and other materials regarding Quality Management, Utilization Management, Case Management, Care Coordination, Credentialing, and Members' Rights & Responsibilities (approximately 250 documents). This evidence spans a period of 2 years and the majority of the evidence has to be reviewed and approved by our Medical Management Quality Committee ("MMQC"), Integrated Health Management Quality Committee ("IHMQC"), and Clinical Advisory Committee ("CAC").

#### **Network Adequacy and Credentialing:**

Same as M/S

Additionally, NCQA performs an audit of a random sample of denials, appeals, case management, and credentialing cases (approximately 350 records).

Cigna maintains one credentialing committee for the review of providers entering the network. Cigna does not routinely track credentialing exceptions for either M/S or MH/SUD Network Providers. Network Providers are recredentialed on a three-year cycle as required by NCQA.

NCQA Accreditation standards require that the organization maintain sufficient numbers and types of behavioral health, primary care and specialty care practitioners in its network. NCQA does not specifically dictate what the appropriate number/type should be. As a result, Cigna conducts review of its Network Adequacy standards at least annually to ensure requirements are sufficient for customer needs. Such analysis reviews external benchmarks (e.g., state laws or CMS requirements) as well as internal review of supply/demand and network adequacy enrollee complaints. Network adequacy analysis considers: geographic area, time/distance standards, provider/enrollee ratio, provider type and/or specialty and supply/demand.

Cigna's Quality Programs and Accreditation team defines quality monitoring standards and provides guidance in initiating improvement initiatives when deficiencies are identified. Quality studies are designed and documented to objectively and systematically monitor, evaluate and improve the quality and appropriateness of care and service. Monitoring and driving improvements in quality of care

and service to our customers is an integral component of Behavioral Accreditation, which reflects the Cigna commitment to continuous quality improvement throughout the organization.

For both its M/S provider network and its MH/SUD provider network, Cigna establishes and monitors clinically appropriate: (1) provider to customer ratios by provider type and/or specialty in urban, suburban and rural geographic regions; (2) time/distance standards for accessing the various provider types and/or specialties located within urban, suburban and rural geographic regions; and (3) appointment wait times for emergency care, urgent care and routine outpatient care for the various provider types and/or specialties, as prescribed by NCQA.

Assessing supply and demand of M/S and MH/SUD facilities are based upon the same indicators including, but not limited to, NCQA and NAIC network adequacy and access standards focused on distribution of provider types within geographic regions (i.e. zip codes); plan population density within geographic regions (i.e. zip codes); time and/or distance to access provider type within urban, suburban and rural areas; appointment wait times for emergent, urgent and routine visits; customer satisfaction surveys; and customer complaint data.

Ratio of Providers to Customers: Providers to customer ratios are normally calculated with the Provider count constant at 1, where the Provider count is based on unique Provider and the Customer count is based on customer's home zip code (students may also

provide their school zipcode at the time of enrollment). To convert to a ratio in this format, Cigna divides the customer count by the Provider count. For example, for an area with 3,000 customers and 30 Providers, – the ratio would be 1:100.

In remote or rural areas, occasionally geographic availability guidelines are not able to be met due to lack of, or absence of, qualified Practitioners and/or Providers. The organization may need to alter the standard based on local availability. Supporting documentation that such situation exists must be supplied along with the proposed guideline changes to the appropriate Quality Committee for approval. Annually, the Quality Management team reviews and assesses the behavioral health care professional network to determine if goals are met and if the network is robust enough to meet the needs of its customers. NCQA requires certain measures to assess availability for urban/suburban, rural, and ratios (behavioral health care professional to customers) across its networks. Likewise, the Network team reviews and assesses the medical health care professional network to determine if goals are met in 90% of the zip codes within the service area for each provider specialty category for PCPs, High Volume Specialist, High Impact Specialists, and Hospitals.

#### Reimbursement:

Cigna's in-network provider reimbursement methodology, exclusive of DRG reimbursement is based upon factors including, but not limited to: geographic market (i.e. market rate and payment type for provider type and/or specialty); type of provider (i.e. hospital,

#### **Reimbursement:**

Same as M/S

clinic and practitioner) and/or specialty; supply of provider type and/or specialty; network adequacy and current Medicare reimbursement rates. All staff participating in a contract negotiation are trained on internal Cigna policies and procedures, and have access to necessary tools to negotiate and develop appropriate reimbursement rates based on standard methodologies, provider specific reimbursement requests and escalate for justification and approval of any deviations.

Concurrent with the negotiation or immediately thereafter, provider credentialing will be completed by Cigna (or other such delegate of credentialing). The provider must successfully meet Cigna credentialing requirements before the contract may be fully executed. CAQH is utilized to obtain most individual practitioner credentialing related information, expediting the credentialing process while Cigna adhering to all state credentialing review timelines. Upon finalization and successful credentialing, the provider agreement is executed and their participation in the Ciana network(s) begins on the applicable effective date. Specific Factors triggering the application of Network Adequacy standards, credentialing, and reimbursement are detailed below.

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.

#### Medical/Surgical: MH/SUD: Network adequacy: Network adequacy: Cigna considers the composition of its Same as M/S current medical/surgical network providers and MH/SUD network providers by provider type and/or specialty, in addition to census (membership) data, to ensure it maintains an adequate medical/surgical provider network and an adequate MH/SUD provider network to meet the clinical needs of its customers. Cigna conducts oversight and monitoring of the adequacy of its M/S provider network(s) and MH/SUD provider network to assess whether they are meeting its internal and regulatory driven network access standards. When access to care standards are not met, Ciana engages in active recruitment of the relevant provider type and/or specialty at issue. Cigna conducts an annual analysis of its network adequacy requirements, and Cigna's medical and behavioral networks meet the company's established access to care standards in urban, suburban, and rural areas. In plans without an out of network benefit, in the event an enrollee cannot secure a provider or appointment within a reasonable time/distance or with reasonable appointment availability Evernorth Behavioral Health ("EBH") will authorize out-of-network services at the in-network benefit level. Enrollees are able to receive assistance in locating a

provider or appointment by contacting the phone number on the back of their ID card. In the event the enrollee and/or a Cigna representative cannot locate a provider/appointment within the acceptable time/distance standards a request can be made for out-of-network care at the in-network benefit level for plans without out of network benefits.

As an additional way of ensuring meaningful access to services, Cigna also measures, consistent with NCQA standards, accessibility of care to MH/SUD providers annually using findings from enrollee surveys and complaints and by measuring results against the accessibility standards and metrics. Cigna uses the continuous quality improvement (CQI) process to identify opportunities for improvement. Cigna has reviewed and rendered uniform, where appropriate, its M/S and MH/SUD network adequacy policies and procedures to ensure comparability across M/S and MH/SUD providers. These policies and procedures are reviewed at least annually to ensure the continued sufficiency of the standards in meeting enrollees' needs. Ciana uses a combined network adequacy policy and a similar reporting template is used for both M/S and MH/SUD benefits.

#### **Credentialing:**

Credentialing criteria for both M/S and MH/SUD Network Providers includes the following standard requirements: (1) signed agreement to participate (2) signed application and provider attestation (3) verification of unrestricted state medical license with appropriate licensing agency; (4) verification of valid, unrestricted DEA certificate (if applicable); (5) verification of full,

#### **Credentialing:**

unrestricted admitting privileges at a Cigna participating hospital; (6) verification Board certification, (if applicable); (7) verification of highest level of education and training, if not board certified; (8) review and verification of malpractice claims history; (9) review of work history; (10) verification of adequate malpractice insurance; and (11) verification of prior and current sanction activities Additional criteria may be applicable pursuant to state credentialing and licensing requirements.

#### **Reimbursement:**

Whether for initial negotiation or renegotiation, Cigna's Network Provider reimbursement methodology for MH/SUD and M/S Network Providers are based upon the same array of factors. Renegotiations of reimbursement rates are conducted according to the terms of the contract, or if not specified in the contract, they are conducted at the request of either party. The number of Network Providers (Individual, Group or Facility) joining or already part of the network does not factor into initial rate offerings. M/S and MH/SUD facilities may be reimbursed per diem, Diagnosis Related Group or case rate. Per diem reimbursement involves a flat dollar amount for each day as reimbursement for the service. DRG reimbursement is based upon Medicare DRG calculations, which assign payment levels to each DRG based on the average cost of treatment. Case rates, also referred to as flat rates, describe a reimbursement structure in which providers receive a flat reimbursement rate for every patient visit, regardless of the service (most often utilized in urgent care). Ciana does not determine or mandate the

#### **Reimbursement:**

reimbursement type; selection of reimbursement type is determined by the facility. Generally, M/S facility providers request DRG reimbursement, while MH/SUD facility providers request per diem reimbursement. More than 90% of MH/SUD Provider Network contracts reflect per diem reimbursement. The evidentiary factors taken into consideration in the negotiation of the per-diem rate are not weighted or prioritized one more than the other; however, additional consideration may be given to meet network adequacy standards.

Factors for reimbursement negotiation include: (1) Geographic market, which may be adjusted based upon Medicare Geographical Practice Cost Index ("GPCI") Geographic Practice Cost Index (GPCI) reflects the relative cost of practicing in a locality against a national average. Each relative value is multiplied by the corresponding GPCI. The three component factors are then accumulated to arrive at an adjusted amount. This amount is then multiplied by the conversion factor to establish the Medicare full fee schedule amount in the Medicare Physician Fee Schedule Data Base (MPFSDB). CMS performs calculations on the fee schedule, with the exception of carrier-priced procedure codes, and provides fee schedule calculations to the Medicare Administrative Contractors (MACs). Geographic Practice Cost Index is not weighted for purposes of per diem reimbursement; (2) Type of provider and/or specialty (e.g. physician practitioner v. non-physician practitioner v. facility); Provider types are dependent upon state licensing and credentialing requirements as outlined by the

applicable state or NCQA. Cigna does not weight provider types or designate any additional provider and/or specialty designations (e.g. physician practitioner v. non-physician practitioner); (3) Supply of provider type and/or specialty. Provider specific fee schedules are used for multi-specialty specialty groups or unique specialty groups where reimbursement terms must be customized to meet the needs of that group or specialty. Provider specific or specialty fee schedules are used to retain providers if the providers are needed to meet network access requirements and/or increase membership. Supply of provider type and/or specialty are not weighted in relation to the other evidentiary standards for purposes of per diem reimbursement; (4) Network need and/or demand for provider type and/or specialty. Network need and/or demand for provider type or specialty is defined by state adequacy requirements. Cigna contracts with practitioners and providers across all networks and for all product lines to meet the availability and cultural needs and preferences of customers, establishes availability standards and assesses its networks against those standards articulated in Cigna's Measuring Availability of Practitioners and Providers Policy. Need and/or demand for provider type and/or specialty are not weighted in relation to the other evidentiary standards for purposes of per diem reimbursement: (5) Trainina. experience and licensure of providers billing for professional services under the facility agreement. Training, experience and licensure of providers billing for professional services under the facility agreement are not specifically weighted in relation to the other evidentiary

standards for purposes of per diem reimbursement; (6) Medicare reimbursement rates for codes with assigned Medicare Relative Value Unit ("RVU"). RVUs are the basis of the RBRVS system. Unit values are assigned to each service (CPT code) by area of specialty and for some codes, different RVUs for site of service: facility and non-facility. RVUs are not weighted for per diem reimbursement;

Cigna utilizes the Medicare Pricing Tool to determine if the provider's (current) rates are above the defined Medicare Baselines. The minimum standards are designated as a percentage of Medicare reimbursement, according to licensure and Medicare locality. Cigna uses standard Medicare Resource Based Relative Value Scale ("RBRVS"), a CMS created reimbursement methodology to reimburse providers for members covered under the Medicare program and as a baseline for commercial reimbursement rates. Cigna's RBRVS methodology calculates the allowable fee for a covered service. Cigna RBRVS is set annually:

[(Work RVU x Work GPCI) + (Practice RVU x Practice GPCI) +

(Malpractice RVU x Malpractice GPCI)] x Conversion Factor = Reimbursement

RVUs are the basis of the RBRVS system. Unit values are assigned to each service (CPT code) by area of specialty and for some codes, different RVUs for site of service: facility and non-facility. Three components are used to make up a total RVU (1) Physician's work – This component accounts for the providers time, technical skill, mental effort, and physiological stress; (2) Practice expense

- This component includes office rent, wages, supplies, equipment; (3) Malpractice Expense - This component includes professional liability insurance cost. To fill gaps for codes not covered by RBRVS methodology Cigna uses relative values assigned by Optum (Ingenix) for M/S services. Optum (Ingenix), is a third party health data company, that uses the same methodology originally used to develop the values for Medicare covered services. For those services that cannot be valued using a resourcebased methodology, values have been developed using alternative methodologies proprietary to Optum (Ingenix). In an RBRVS calculation, each component of an RVU is multiplied by its GPCI then totaled and multiplied by the conversion factor to determine the fee or payment. Cigna uses the same GPCIs as Medicare. There are approximately 89 GPCIs. Ciana uses Optum (Inaenix) values to fill gaps for codes not covered by RBRVS methodology.

Facility rate categories are industry standard with the market and economy dictating rates for both M/S and MH/SUD facilities. Cigna utilizes Medicare's resource-based relative value scale (RBRVS) calculation (OP-BH & Med). This calculation is premised on the principle that payments for services should vary with the resource cost for providing the services. In each instance, the fee schedule is separately reviewed and negotiated.

For DRG reimbursement, weighting is not calculated within the contract or at the time of contract rate negotiation, but instead occurs at the time of payment as DRG reimbursement is dependent on a variety of variable factors such as patient

contracted factor = reimbursement.  Step 4 - Provide the comparative analyses	domonatesting that the processes
203 has a factor 17; CMS DRG weight x	
the reimbursement, based on the factor in the contract; by way of example: DRG	
that DRG information is used to calculate	
"groups it" into the correct DRG. Then	
takes the information from the claim and	
CMS grouping software (Optum) that	
are negotiated separately. Cigna utilizes	
distinguished in the contract and rates	
population and type of care are	
contracts at a per diem rate, the	
age and diagnosis. When behavioral	
age and diagnosis. When behavioral	

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.

Medical/Surgical:	MH/SUD:
In writing Analysis:	
Network Adequacy:	Network Adequacy:
Both MH/SUD and M/S negotiations are based upon provider and information availability at a single point in-time.  Network adequacy standards (Network	

Need) is a contributing factor for both MH/SUD and M/S providers during a reimbursement negotiation. It is important to note that different providers and facilities have vastly different negotiating or so-called bargaining power. A provider's bargaining power depends on several factors of which cannot simply be reduced to supply and demand including the provider's size (e.g., a large statewide or national hospital system vs. an individual solo practitioner); the scarcity or the "supply" of that provider type or specialty; and the reputation, name recognition, and/or quality of the provider.

As expected, providers and facilities that for a variety of reasons have more bargaining power are able to negotiate higher reimbursement. Cigna measures accessibility of care to behavioral (prescriber and non-prescriber), PCP, and High-Impact/High-Volume SPC providers using findings from customer surveys and complaints, and by measuring results against the accessibility standards and metrics annually. Cigna uses the continuous quality improvement ("CQI") process to identify opportunities for improvement and when network adequacy gaps are identified and brought to the attention of the Behavioral Health Provider Operations Program Management Team (for either provider or facility). That team researches available providers and prioritizes recruitment efforts. The recruitment timeline is as follows:

If Cigna identifies a network adequacy deficiency, it attempts to remediate the deficiency. The identified potential provider may decline participation in the network or may not respond to

recruitment efforts. If Cigna identifies a non-contracted provider needed for adequacy/accessibility, it may offer higher rates than what would otherwise be standard in order to close the gap. NCQA does not prescribe goals for geo access. Cigna uses a 90% standard, which aligns with CMS network adequacy requirements, which require that 90% of customers have access to providers based on network adequacy access requirements for time and distance standards.

Cigna monitors network adequacy on at least an annual basis and creates recruitment and corrective action plans to address any deficiencies. In many instances, deficiencies are a result of insufficient availability of providers/facilities. Both MH/SUD and M/S networks are held to the same 90% standard. In most instances inability to meet the 90% threshold is related to insufficient provider availability. Lack of providers/facilities tends to impact behavioral more than medical. Cigna actively recruits providers in areas where there may be access deficiencies. In some cases, not enough providers exist in a given geographic area and thus Cigna cannot meet a network adequacy standard due to provider unavailability. In such situations, Cigna takes steps to ensure that an enrollee in a plan using this network would be able to receive medically necessary services from an out of network provider, and the services would be treated as in-network for purposes of cost-sharing or other requirements.

#### **Credentialing:**

Cigna's methodology for credentialing for M/S and MH/SUD physician providers are the same. Cigna credentialing standards for licensed physicians follows NCQA, CMS, state and federal requirements and guidelines for each provider and/or specialty type. Cigna does not maintain separate standards for MH/SUD providers. Moreover, the standard credentialing process is used for both licensed physician providers and licensed non-physician providers, whether they are M/S or MH/SUD providers. Re-credentialing is required every three years for all providers, and except for work history and education and training verification, requires providers to meet the same criteria as the initial credentialing process, unless a new specialty is being requested.

The credentialing application process is consistent between physicians and facilities providing M/S and MH/SUD services and the required licensing, experience, CAQH application and verifications are indistinguishable. No additional Ciana-specific credentialina requirements are applied to either M/S or MH/SUD physician providers, and, as relevant for certain MH/SUD services or specialties, Cigna does not require that MH/SUD practitioners or facilities be licensed or accredited if such a license or accreditation would not be required by state law. Consistency in credentialing standards and process evidences compliance with the NQTL in-writing requirement.

## Credentialing:

#### **Provider Reimbursement**

Whether for initial negotiation or renegotiation, Cigna uses its standard in-

#### **Provider Reimbursement**

network provider reimbursement methodology for MH/SUD and M/S providers. Network adequacy deficiencies (Network Need) is always considered when negotiating reimbursement rates. Standard reimbursement rates for inpatient and outpatient services for both M/S and MH/SUD providers are set based upon standard fee schedules, which are developed for facilities, physicians and non-physicians by state or region and reflect geographic variations within that state or region. Provider-specific fee schedules are developed based upon the professional or facility's negotiation request or business need, including the satisfaction of network adequacy requirements. Cigna's preferred standard is to reimburse the same rates across all plans/products. M/S contracts have the option to pay plans differently, while BH pays the same for all plans. This approach provides more favorable rates for MH/SUD providers. For example, BH pays the same rate for a Medicare provider as it does for a commercial provider. Rates may be negotiated differently depending upon plan if requested.

In determining any rate in both the M/S and MH/SUD facility agreements, Cigna assesses supply and demand of provider types and/or specialties based upon the same indicators including, but not limited to NCQA network adequacy and access standards focused on distribution of provider types within geographic regions (i.e. zip codes); plan population density within geographic regions (i.e. zip codes); time and/or distance to access provider type within urban, suburban and rural areas; appointment wait times for emergent, urgent and routine visits;

customer satisfaction surveys; and customer complaint data. That is, Cigna's reimbursement rate development and negotiation processes are ultimately designed to ensure achievement of its adequacy standards for MH/SUD and M/S providers, and any departure from the standard fee schedules is informed by market demand, which may include, for example, the need to maintain, or achieve, network adequacy for a provider type in a particular geographic area.

#### Facility Reimbursement – Inpatient

In-network facility-based services which are not reimbursed on an assigned diagnosis-related group (DRG) or case rate basis may generally be reimbursed on a per diem or discount basis. Currently, M/S has many more DRG contracts while a small minority of MH/SUD contracts are paid as DRG or case rate. Specifically, M/S paid just under 60% of admissions last year under DRGs and 20% as per-diem, and 20% as a percent of charges. MH/SUD are essentially 100% per-diem, as MH/SUD contracts do not have any significant case rates or percent of charges contracts. DRG (i.e. case rate) reimbursement rates generally do not exist for MH/SUD in-network inpatient services because unlike certain routine medical inpatient procedures (i.e. vaginal deliveries; cesarean deliveries; appendectomies, etc.), MH/SUD inpatient stays vary depending upon the unique clinical needs, circumstances and complexities of the individual patient (i.e. patient's insight or lack of insight into their illness; patient motivation to receive treatment; comorbidity, etc.

Per diem reimbursement for both M/S and MH/SUD facility-based services are based upon the following factors and accompanying evidentiary standards: (1) geographic market, which may be adjusted based upon Medicare Geographical Practice Cost Index ("GPCI"); (2) type of provider and/or specialty (e.g. physician practitioner v. non-physician practitioner v. facility); (3) supply of provider type and/or specialty; (4) network need and/or demand for provider type and/or specialty; (5) Medicare reimbursement rates for codes with assigned Medicare Relative Value Unit ("RVU"); and (6) Training, experience and licensure of providers billing for professional services under the facility agreement.

Cigna's methodology and process for negotiating in-network provider reimbursements for M/S and MH/SUD services within a classification of benefits are comparable and no more stringent for MH/SUD services than for M/S services within the same classification of benefits as written. Cigna also follows a comparable process in determining payment rates for non-physician providers for both M/S and MH/SUD benefits. While there is variation in type of reimbursement methodology for facility reimbursement, Cigna's Network Providers choose which methodology (DRG, Per Diem or Case Rate) will apply and the processes, factors and evidentiary standards applicable to each methodology is applied to M/S and MH/SUD providers consistently. In this process, variables including market demand, provider specialty and availability and frequency of requests for provider fee increases may result in differentials in reimbursement rates across

medical/surgical and MH/SUD provider types.

#### **In Operation Analysis**

#### In operation – data

#### M/S:

This comparative analysis was drafted based on Cigna Credentialing and Network Access Reporting provided below.

Metric	Medical
Time/Distance Report	PCP = 100% (met) Specialist = 98% - 100% (met)
Provider/Enrolle e Ratio	PCP Ratio (1 PCP: 300 Members): Met Specialist Ratio except ophthamology and OBGYN (1 Spec: 10,000 Members): Met Specialist Ratio ophthamology and OBGYN Specialist Ratio (1 Spec: 2,000 Members): Met

Credentialing	Medical	%
Total number of requests	55631	
Total approved	55447	99.6 7%
Total denied	184	0.33 %

#### In operation – data

#### MH/SUD:

This comparative analysis was drafted based on Cigna Credentialing and Network Access Reporting provided below.

Metric	Behavioral
Time/Distance Report	Master's Level Clinician: 97% (met) Psychologist: 83% (not met) Physician 90% (met)
Provider/Enrollee Ratio	Masters Ratio (1 Masters Level Clinician: 800 Members): Met Psychologist Ratio (1 Psychologist: 1,500 Members): Met Prescriber Ratio (1 Psychiatrist/NP: 1,500 Members): Met Inpatient Facility Ratio (1 Facility: 10,000 Members): Met Residential Facility Ratio (1 Facility: 20,000 Members): Met Ambulatory Program Ratio (1

Total number of denials appealed	24	13%		Program: 10 Members):	
Number of appeals overturned	9	38%			
Number of appeals upheld	15	62.5 %			
List Top 5 Credentialing Denial Reasons	1. Malpractice Issue 2. License				
	Issue 3. Board		Credentialing	Behavior al	%
	Certification Issue 4. Hospital		Total number of requests	45271	
	Privileges 5. Govt/Federal		Total approved	45211	99.8 7%
Avorago	Business Excl		Total denied	60	0.13
Average credentialing approval TAT	25.24 days		Total number of denials appealed	2	0.03
Average credentialing	07.44		Number of appeals overturned	1	0.17
denial TAT	87.66 days		Number of appeals upheld	1	0.17
			List Top 5 Credentialing Denial Reasons	1. License Issue 2. Malpract ice Issue 3. 4. 5.	

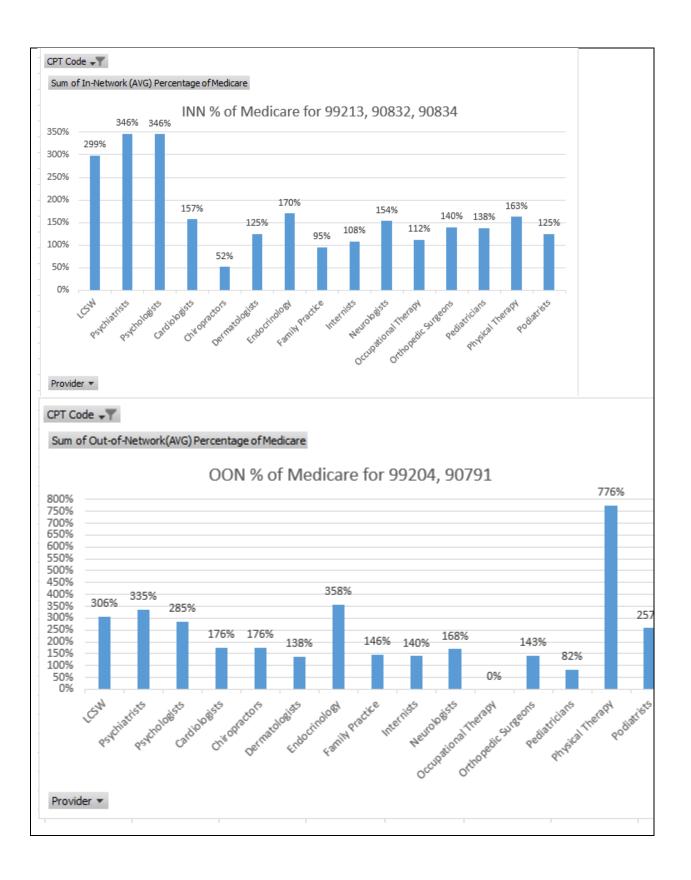
Average credentialing approval TAT	21.95 days	
Average credentialing denial TAT	87.86 days	

### **WELLFLEET**

Wellfleet performed a comparison of average out of network claims payments during calendar year 2023 as a percentage of Medicare rates for the Wellfleet book of business for nine (9) CPT codes across three (3) MedSurg primary care physician types, five (5) MedSurg physician specialty types, four (4) MedSurg ancillary types and, one (1) MHSUD physician type, and two (2) MHSUD ancillary types. The results are as follows:

- 99203: There were insufficient MH/SUD 99203 claims except for psychologists resulting on 373% more than Medicare, whereas the MedSurg claims for 99203 were from 114% to 241% of Medicare. No concerning differences were noted.
- 99213, 90832 & 90834: MH/SUD psychiatrists, social workers and psychologists were reimbursed the most (> 500% of Medicare) vs. MedSurg PCPs (120-188% of Medicare) vs. MedSurg specialists (87%-311% of Medicare). The significant results for both M/S and MH/SUD show reimbursement substantially more for MHSUD.
- 99204 & 90791: MedSurg shows significant outlier of Physical Therapy at 776% of Medicare whereas the rest of MedSurg shows average of 140-358% of Medicare. MH/SUD significant results were both reimbursed >285% of Medicare. No concerning differences were noted.
- 99214, 90837 & 90830: MHSUD claims show a significant % of Medicare reimbursed more than that of MedSurg providers.





### <u>In operation – compa</u>rative analysis:

Network adequacy: A review of Cigna's Network Adequacy reports for Cigna's national network revealed sufficient access to M/S and MH/SUD providers. Cigna meets adequacy and accessibility requirements for M/S and MH/SUD providers using comparable standards, with M/S providers subject to more stringent standards. At present, Ciana meets all provider ratio access requirements for Masters Level Clinicians, Psychologist/Nurse Practitioners with prescribing privileges, Physicians, Inpatient Facility and Residential Facility for the MH/SUD Network. Cigna also meets all provider ratio access requirements for adult and pediatric PCP; high volume specialty including cardiology, dermatology, ophthalmology, and orthopedics; and high impact specialty for hematology/oncology, infectious disease, nephrology, neurology and pulmonary. Holistically, when reviewing the current snapshot of both the M/S and MH/SUD networks, Ciana also meets provider access radius requirements. When reviewed individually by state, deficiencies are noted in rural areas such as Alaska, Idaho, Montana, South Dakota and Wyoming in both the M/S and MH/SUD Networks. Lastly, Cigna reviewed the percentages of exceptions for obtaining out-of-network M/S and MH/SUD services at the in-network benefit level to ensure operational parity compliance. Data revealed a significantly larger number of M/S network exceptions denied including both medical necessity and administrative denials than denials of MH/SUD network exceptions.

**Credentialing:** An "in operation" review of Cigna's credentialing applications, approvals and denials of providers revealed no disparate outcomes in credentialing approvals or denials as between M/S and MH/SUD physician providers. The average time it took Cigna to review and approve a credentialing application for both M/S and MH/SUD providers was 23.6 days, a 25 day approval average for M/S providers and a shorter 22 day approval average for MH/SUD providers. The average time it took Cigna to review and deny a credentialing application for both M/S and MH/SUD providers was 87 days. These credentialing process metrics indicate a comparable process in-operation based on the time to review, a significantly lower amount of denials of MH/SUD provider credentialing applications, and comparable incidences of denials of MH/SUD and M/S provider credentialing denial overturns on appeal. Consequently, Cigna concludes that the NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits.

### Reimbursement:

### **Wellfleet**

In terms of operational parity compliance, Wellfleet has assessed the reimbursement rates paid across its book-of-business by reference to reimbursement data in 2023. In its assessment, Wellfleet reviewed CPT codes for ancillary, PCP, and specialists for MHSUD & MedSurg. Wellfleet has determined that the reimbursement rates are comparable and not more stringent once Wellfleet eliminates the high outlier claims for ancillary therapy provider types. By contrast, MH/SUD providers are reimbursed at

a higher or comparable average for CPT codes 99203, 99213, 99214, 90832, 90834, 90837, & 90839, compared to M/S providers.

The analysis of the 2023 claims reimbursement demonstrates the payment versus Medicare rates for the same provider types and CPT codes did not provide concerns regarding possible issues with disparities in payment between similar types of MH/SUD versus MedSurg providers. Moreover, as demonstrated by the bar graphs, the reimbursement rates as a percentage of Medicare for MH/SUD providers are comparable or higher than the reimbursement rates as a percentage of Medicare for MedSurg providers, apart from therapists, who are a significant outlier for specified code groups for both in-network and out-of-network reimbursement. Therefore, in operation, the processes, standards, factors, and sources used to apply reimbursement to MH/SUD services is comparable and not more stringent than the processes, standards, factors, and sources used to apply reimbursement to MedSurg services. Wellfleet concludes that it applies reimbursement either equally or less stringently for MH/SUD providers than it does for MedSurg providers. While operational outcomes are not determinative of NQTL compliance, and a plan may comply with the NQTL requirement notwithstanding a disparate outcome for an NQTL applied to MH/SUD benefits as compared to M/S benefits, comparable outcomes can help evidence compliance with the in-operation component of the NQTL requirement.

### <u>Cigna</u>

In December 2021, Cigna conducted a comparison of DRG reimbursement to innetwork M/S facilities compared to per diem used for MH/SUD in-network facility-based services. To conduct the comparative analysis of in-network facility reimbursement by DRG payment system methodology versus per diem payment methodology, Cigna did not target a specific facility's DRGs, but rather claim line data aligning a DRG to a diagnostic code only. The top 35 diagnostic codes were obtained from the dataset through a group by statement ordered descending to identify the 35 diagnostic codes with the highest allowed spend for the time period of the analysis; FY2020. An average allowed amount was derived at the diagnostic code level for a comparison of Avg. Per Day, Avg. Per Unit, and Avg. Per Member from claim line data designated as Behavioral compared to claim line date designated as Medical. The analysis was not inclusive of expected lengths of stay.

Cigna reviewed the DRGs for M/S admissions to determine the "daily" rate average for inpatient admission based on the expected length of the DRG. To unpack the DRG rate, Cigna applied this back to the length of stay that is contemplated by the respective DRGs, as they are different for every diagnosis. Once the DRG daily rate was determined, Cigna compared it to the MH/SUD reimbursement for a hospital bed day. Specifically for the comparison, Cigna utilized the most comparable lists of admission diagnoses between M/S and MH/SUD services which included the top 35 inpatient diagnosis codes. Cigna's data warehouse cross-walked claims using logic to identify MH/SUD spend apart from M/S spend so like services would not be included in the comparison when reviewing by diagnosis. This logic ensured a singular

classification. For example: Primary diagnosis of F329 for Behavioral may align to an Inpatient admission with a bed day per diem, and the same diagnosis for Medical may align to an ER Level 1 case rate. Given the vast differences between M/S and MH/SUD inpatient stays and variation of diagnoses, singular classifications were omitted. Cigna's MH/SUD network does not provide separate reimbursements for different plans, so the reimbursement diagnosis codes and average units were based on Cigna's commercial book of business. Inpatient admissions included all of the MH/SUD IP levels of care: Inpatient Behavioral Health Level of Care, Adult, Inpatient Behavioral Health Level of Care, Child or Adolescent, Eating Disorders, Inpatient Behavioral Health Level of Care and inpatient detox level of care Substance Use Disorder inpatient levels of care which included ASAM Level 4 and ASAM Level 3.7.

The facility reimbursement comparative analysis reflects that, on average, Cigna applied a 54.6% discount for MH/SUD services and 50.6% discount for M/S services resulting in a 4% spread between the two, which can be categorized as comparable and not resulting in a disparate outcome. The direct DRG/Per Diem comparison resulted in a difference of \$7,133 average per day difference between M/S and MH/SUD inpatient stays, in favor of the MH/SUD per diem stay receiving higher reimbursement.

While the comparison of two distinct methodologies is inherently challenging due to the material differences in how facility-based services are reimbursed and the DRG-Per Diem comparison evidences a difference in the MH/SUD and M/S reimbursement rates, this does not indicate a disadvantageously disparate outcome for inpatient stays. In fact, in this instance the comparison illustrates a higher average per unit and per day cost for MH/SUD per diem facilities than M/S facilities paid the DRG rate. As a general matter, due to variability in length of stay for MH/SUD benefits per diem reimbursements are more favorable for MH/SUD than are DRGs. In other words, if Cigna sought to impose DRGs on MH/SUD benefits it would likely reduce reimbursement rates because the course of treatment is relatively unpredictable for MH/SUD conditions as opposed to M/S conditions. This presupposition aligns with the fact that MH/SUD facilities have rejected DRG reimbursement. It can be assumed a lower reimbursement rate could impact accessibility to in-network providers and Cigna's network admissions criteria, itself the relevant NQTL. However the DRG-Per Diem comparison coupled with Cigna's comparable out-of-network utilization over the recent measurement period across MH/SUD and M/S benefits and the achievement of applicable network adequacy requirements for MH/SUD and M/S providers, respectively, evidences comparability.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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

Cigna assesses supply and demand of both M/S and MH/SUD provider types and/or specialties based upon the same indicators including NCQA and NAIC, and federal/state, network adequacy and access standards focused on distribution of provider types within geographic regions (i.e. zip codes); plan population density within geographic regions (i.e. zip codes); time and/or distance to access provider type within urban, suburban and rural areas; appointment wait times for emergent, urgent and routine visits; customer satisfaction surveys; customer complaint data. The conclusion of such assessments may result in an increase or decrease in the provider's reimbursement rate.

Over the past several years Cigna has conducted a comprehensive review of its MH/SUD network admission standards, including network access standards, contracting processes and reimbursement rates applicable to Network Providers. Any variances in contracting processes as well as a range of reimbursement rates based on percentages of Medicare RVUs as compared to M/S reimbursement rates were identified and analyzed for adherence to the NQTL requirement.

In connection with its ongoing NQTL compliance efforts, Ciana has taken proactive, additional steps to continually ensure the comparability of standards for provider admissions into the MH/SUD provider network, including reimbursement rate methodology, to ensure the processes, strategies and evidentiary standards implemented are not more stringent for MH/SUD services than M/S services. First, Cigna has aligned contracting policies and processes and rolled out a facility reimbursement strategy shifting from reactively addressing disparate outcomes between M/S and MH/SUD reimbursement rates to proactively updating reimbursement rates for facilities for which rate increases have not been requested in the past two years. As evidence of Cigna's success in establishing rates that help ensure the acquisition and retention of providers in its MH/SUD network, the facility rate renegotiation report for January 1, 2020 through March 31, 2021 documented 487 provider renegotiations, of which 446 negotiations were completed, 11 are currently in process and 31 were discontinued due to provider's non-responsiveness, 2 discontinued due to a Special Investigations audit, and 1 was discontinued due to the facility requesting fees for services for which they lacked a state-required license. Cigna has also reviewed more than 10,000 reimbursement rates for outpatient based fee schedules. The outpatient rate negotiation report for January 1, 2020 through March 31, 2021 includes a total of 10,559 rate increases with 9,497 completed and 933 were denied or incomplete due to the non-responsiveness of the provider.

Network adequacy standards for MH/SUD providers are comparable to similar M/S specialists. In most instances the behavioral network adequacy standards require a

customer to travel fewer miles to see a MS/SUD specialist as compared to an M/S specialist, effectively making MH/SUD providers more accessible to customers as compared to medical specialists. Currently, for both M/S and MH/SUD providers, at least 90% of enrollees are required to have the designated access to meet Cigna's network adequacy standard.

In addition to rolling out reimbursement upgrades for so-called stagnant contracts (that is, facility contracts that have not requested an increase in rates within the past 5 years and have remained at the same percentage of Medicare), facility based reimbursement is transitioning from a service level approach of negotiation to a total cost of care to address both competitiveness through the use of pricing benchmarks and market based analysis. This approach aligns with the methodology and process for updating inpatient reimbursement rates for hospitals providing M/S services. Cigna is currently creating a database including various benchmarking sources for the comparison of in-network rates against pricing benchmarks to assess affordability and to ensure the closure of any unsubstantiated gaps in reimbursement rates. Lastly, for new providers entering the network, Cigna has aligned the contracting process and has developed and implemented a standard reimbursement methodology for the negotiation of MH/SUD reimbursement rates with M/S contracting and reimbursement methodology. Such alignment includes the implementation of standard fee schedules and the implementation of established outpatient facility and practitioner fee schedules and exceptions to standard fee schedule requests in order to contract with and retain providers essential to the integrity of the MH/SUD provider network.

An analysis of Wellfleet's in-network payments versus Medicare rates for the same provider types and CPT codes did not provide concerns regarding possible issues with disparities in payment between similar types of MH/SUD versus M/S providers. Moreover, as demonstrated by the bar graphs in Step 4, the INN reimbursement rates as a percentage of Medicare for MH/SUD providers is comparable to the OON reimbursement rates as a percentage of Medicare for M/S providers, with the exception of therapists, who are a significant outlier for specified code groups for both in-network and out-of-network reimbursement. Therefore, in operation, the processes, standards, factors, and sources used to apply OON reimbursement to MH/SUD services is comparable and not more stringent than the processes, standards, factors, and sources used to apply OON reimbursement to M/S services. Wellfleet concludes that it applies reimbursement either equally or less stringently for MH/SUD providers than it does for M/S providers.

Consistent with the NQTL requirement for comparability/stringency, Cigna has confirmed that standards for provider admission into the MH/SUD provider network, including credentialing, adequacy, and provider reimbursement rates for inpatient and outpatient services are comparable to, and applied no more stringently than, that of the M/S provider network as written and in operation. Put differently, Cigna's

network has the ability to meet the MH/SUD services needs of our enrollees by providing reasonable access to a sufficient number of in-network providers for both inpatient and outpatient services.

# 10. <u>Reimbursement for INN Providers, OON Providers, INN Facilities, OON Facilities</u> (separately)

**NQTL Type: Out-of-Network Reimbursement** 

Classification(s): Inpatient, Outpatient, and Emergency (Out-of-network)

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding the NQTL and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

- Provide a clear description of the specific NQTL, plan terms, and policies at issue
- Identify which M/S and MH/SUD benefits are subject to the NQTL

Step 1(a): Provide a clear description of the specific NQTL, plan terms, and policies at issue:

Out-of-network (OON) reimbursement applies to claims where the submitting provider has not entered into a contractual arrangement.

Wellfleet reimburses Out-Of-Network providers through Reasonable and Customary (R&C) methodology. Wellfleet uses Fair Health as our source for Reasonable and Customary (R&C) Data. Wellfleet downloads Fair Health data several times a year and uses that data to reimburse out of network services according to the specific plans out of network benefit level.

After applying R&C, OON outpatient and OON emergency, as well as all original OON inpatient M/S benefit claims are sent to Zelis. Zelis applies Established Reimbursement Schedule (ERS) rates to all OON inpatient, OON outpatient (except ambulance), and OON emergency M/S benefits. Zelis applies their Network rates to any applicable OON inpatient, OON outpatient, and OON emergency M/S benefits for comparison to the ERS rates. Zelis performs the negotiations for out of network claims and after the negotiation is complete the claim is sent back to Wellfleet's Claim Team with the discount applied for processing. The review conducted by Zelis only occurs on M/S claims because Zelis's goal is to obtain a discount or lower the rate for M/S benefits. This process is not applied to outpatient MH/SUD claims.

Step 1 (b): Identify the M/S
benefits/services for which the NQTL is
required:

All out of network benefits and services

Step 1(b): Identify the MH/SUD benefits/services for which the NQTL is required:

All out of network benefits and services

Step 2 – Identify the factors used to determine that the NQTL will apply to mental health or substance use disorder benefits and medical or surgical benefits			
Medical/Surgical:	MH/SUD:		
Factors	Same as M/S		
Factors considered in determining provider reimbursement for <b>Out-of-Network (OON) services</b> :			
1. Provider Type 2. Services and/or Procedures Provided 3. Geographic location 4. Industry Benchmark Rates/Methodology The factors are not weighted. Reimbursement is based on standard fee schedules, which are developed by looking at provider type, the services/procedures provided, and using industry benchmark rates			

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTL to mental health or substance use disorder benefits and medical or surgical benefits.

- 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.
- 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.

Medical/Surgical:	MH/SUD:	
Provider Type     Definition: physician vs. non- physician, specialty	Provider Type     Definition: physician vs. non-physician, specialty	
Evidentiary Standards: The provider type and/or specialty is assessed based upon the provider's credentials, licensure, board certification, education, and training	Evidentiary Standards: The provider type and/or specialty is assessed based upon the provider's credentials, licensure, board certification, education, and training	

<u>Sources:</u> Provider credentialing application and/or claims data (i.e., taxonomy, provider specialty and type codes)

2. Services and/or Procedures Provided <u>Definition:</u> services and/or procedures provided

<u>Evidentiary Standards:</u> Most current version of industry standard code sets, e.g., CPT, HCPCS, etc.

<u>Sources:</u> Most current version of industry standard code sets, e.g., CPT, HCPCS, etc.; claims data (i.e., service/procedure codes)

### 3. Geographic Location

<u>Source:</u> Zip Code of the provider or facility sending the claim

# 4. Industry Benchmark Rates/Methodology

### Sources:

1. Wellfleet uses Fair Health as our source for Reasonable and Customary (R&C) Data. Wellfleet downloads Fair Health data several times a year and uses that data to reimburse out of network services according to the specific plans out of network benefit level. Fair Health's rich data repository and independence make it a valued resource for reliable, objective data. FH® Charge Benchmarks provide up-todate, actionable data based on recent claims from 493 distinct geographic regions nationwide. Fair Health has been consulted by numerous federal officials including those

<u>Sources:</u> Provider credentialing application and/or claims data (i.e., taxonomy, provider specialty and type codes)

 Services and/or Procedures Provided <u>Definition:</u> services and/or procedures provided

<u>Evidentiary Standards:</u> Most current version of industry standard code sets, e.g., CPT, HCPCS, etc.

<u>Sources:</u> Most current version of industry standard code sets, e.g., CPT, HCPCS, etc.; claims data (i.e., service/procedure codes)

### 3. Geographic Location

<u>Source:</u> Zip Code of the provider or facility sending the claim

# 4. Industry Benchmark Rates/Methodology

### Sources:

Wellfleet uses Fair Health as our source for Reasonable and Customary (R&C) Data.
Wellfleet downloads Fair Health data several times a year and uses that data to reimburse out of network services according to the specific plans out of network benefit level.

Fair Health's rich data repository and independence make it a valued resource for reliable, objective data. FH® Charge Benchmarks provide up-to-date, actionable data based on recent claims from 493 distinct geographic regions nationwide. Fair Health has been consulted by numerous federal officials

from the White House, the
Department of Health and
Human Services, the
Department of Labor, the Food
and Drug Administration, the
Centers for Disease Control and
Prevention, the Department of
Commerce, the Department of
Agriculture and the
Congressional Budget Office.
Fair Health data has been used
to address a broad range of
issues including:

- Bureau of Labor Statistics in developing its medical pricing indices.
- Government Accountability Office to support studies of air ambulance and dental service
- Office of National Drug Control Policy under President Obama
- The President's Commission on Combating Drug Addiction and the Opioid Crisis under President Trump

2. Zelis' ERS rates are based on Medicare rates, which are updated annually by CMS and published on the Federal government website.

### **Evidentiary Standards:**

Wellfleet uses Reasonable and Customary (R&C) pricing data to price our out-of-network claims. We consider the total billed charges to all health plans for similar services/supplies by CPT/HCPCS coding within the same region as defined by Zip codes.

including those from the White House, the Department of Health and Human Services, the Department of Labor, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Department of Commerce, the Department of Agriculture and the Congressional Budget Office. Fair Health data has been used to address a broad range of issues including:

- Bureau of Labor Statistics in developing its medical pricing indices.
- Government Accountability Office to support studies of air ambulance and dental service
- Office of National Drug Control Policy under President Obama
- The President's Commission on Combating Drug Addiction and the Opioid Crisis under President Trump

### **Evidentiary Standards:**

Wellfleet uses Reasonable and Customary (R&C) pricing data to price our out-of-network claims. We consider the total billed charges to all health plans for similar services/supplies by CPT/HCPCS coding within the same region as defined by Zip codes.

Zelis uses a percentage of Medicare rates to price our out-of-network claims. Zelis takes each CPT/HCPCS code on the claim and multiplies it by a percentage of the Medicare rate for the same code within the same region as defined by Zip codes.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

- 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.
- 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).
- 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.

MH/SUD: Medical/Surgical: **Determining OON Rates: Determining OON Rates:** 1. Wellfleet applies Reasonable and 1. Wellfleet applies Reasonable and Customary (R&C) reimbursement Customary (R&C) reimbursement rates to all OON outpatient and rates to all OON outpatient and OON emergency M/S benefits OON emergency MH/SUD benefits 2. After applying R&C, OON 2. After applying R&C, OON outpatient and OON emergency, outpatient and OON emergency, as well as all original OON as well as all original OON inpatient inpatient M/S benefit claims are M/S benefit claims (not MH/SUD sent to Zelis claims) are sent to Zelis a. Zelis applies ERS rates to all a. Zelis\* applies their rates to OON inpatient, OON any applicable OON outpatient (except inpatient, OON outpatient, ambulance), and OON and OON emergency M/S emergency M/S benefits. benefits for comparison to b. Zelis applies their Network the ERS rates.

rates to any applicable OON inpatient, OON outpatient, and OON emergency M/S benefits for comparison to the ERS rates.

 Zelis performs the negotiations for out of network claims and after the negotiation is complete the claim is sent back to Wellfleet with the discount applied for processing.

### Out-of-Network Providers Paid at In-Network Level:

In circumstances where a Wellfleet member needs care and there is no In-Network Provider available:

- with the necessary credentials/specialty;
- within a reasonable distance from member;
- accepting new patients (if member would be a new patient);
- within a reasonable appointment wait time; and
- any other material considerations.

Then, Wellfleet shall treat the services by an out-of-network provider as if the services were provided by an in-network provider (i.e., for purposes of calculating the deductible, copayment amount, or coinsurance on the member's plan).

Wellfleet will pay at the In-Network level for treatment by an Out-of-Network Provider, and will calculate the cost sharing amount at the In-Network Provider level, if:

1. There is no In-Network Provider in the Preferred Provider service area available to provide a Preventive Service or treat a member for a specific Covered Injury or Covered Sickness; or \*Zelis doesn't offer ERS for outpatient MH/SUD claims. Zelis' experience has shown that MH/SUD facilities and providers generally will not accept ERS payments. Wellfleet's experience is that MH/SUD facilities and providers generally will accept R&C payments, which tend to be higher than ERS payments.

### Out-of-Network Providers Paid at In-Network Level:

Same as M/S

- 2. The member has an Emergency Medical Condition and receives Emergency Services from an Out-of-Network Provider or facility. The most the Out-of-Network Provider or facility may bill the member is the In-Network cost sharing amount (such as Deductibles, Copayments and Coinsurance). Members cannot be balance billed for these Emergency Services. This includes services members may get after they are in stable condition, unless the Out-of-Network Provider or facility determines that the member can travel using nonmedical or non-emergency transportation, the Out-of-Network Provider satisfies the consent and notice requirements, and the member is in a condition to receive notice of, and to consent to, Out-of-Network Treatment; or
- 3. The member receives non-Emergency Services from an In-Network Hospital or Ambulatory Surgical Center, but certain providers there may be Out-of-Network Providers. In these cases, the most Out-of-Network Providers may bill the member is the In-Network cost sharing amount. This applies to emergency medicine, anesthesia, pathology, radiology, laboratory, neonatology, Assistant Surgeon, hospitalist, or intensivist services. These Out-of-Network Providers can't balance bill the member and may not ask the member to give up their protections not to be balance billed.

If a member received notice from the Out-of-Network Provider of their non-network status at least 72 hours in advance, or if the member makes an appointment within 72 hours of the services being delivered and notice and consent is given on the date of the service, and the member gave written

consent to Treatment, Wellfleet will pay Covered Medical Expenses at the Outof-Network level as shown in the Schedule of Benefits. This notice and consent exception does not apply to ancillary services, which include items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a Physician or non-Physician practitioner; items and services provided by assistant surgeons, hospitalists, and intensivists; diagnostic services, including radiology and laboratory services; and items and services provided by an Outof-Network Provider in circumstances where there is no In-Network Provider who can furnish the item or service at the relevant facility.

For more information refer to the Maryland Specific Out of Network Provider Paid at In Network Level Guideline document located on the Wellfleet Student Website "Forms" tab on this link: <a href="http://wellfleetstudent.com/wp-content/uploads/2022/11/WIC-MD-Out-of-Network-Provider-paid-at-in-network-level-guideline-v11-18-22-final-for-website.pdf">http://wellfleetstudent.com/wp-content/uploads/2022/11/WIC-MD-Out-of-Network-Provider-paid-at-in-network-level-guideline-v11-18-22-final-for-website.pdf</a>

### In writing Analysis:

Wellfleet's policy for payment of out-of-network claims is to pay 80% of the Fair Health Average billed charge, for both M/S and MH/SUD providers. There is a single policy for all provider claims, independent of whether the claim is for an M/S or an MH/SUD provider.

In addition, while Zelis is used as an additional source for M/S services, MH/SUD services are not subject to this additional layer of review by Zelis. For both MH/SUD and M/S OON services, Wellfleet uses Reasonable and Customary (R&C) pricing data to price its out-of-network claims. Wellfleet considers the total billed charges to all health plans for similar services/supplies by CPT/HCPCS coding within the same region as defined by Zip codes. This pricing methodology is the same for MH/SUD and M/S services. However, Zelis's review to obtain a discount is only applied to M/S services. As a result, this NQTL is applied more favorable for MH/SUD benefits because Zelis's review allows for reimbursement rates to be lowered for M/S services, based on

discounts and contractual relationships available to Zelis. This has the overall effect of driving down reimbursement rates for M/S services. However, Zelis's process is not applied to out of network outpatient MH/SUD services, thus, only the R&C rates are applied to MH/SUD services which is generally higher than the ERS payments negotiated by Zelis for M/S services. Therefore, because there is process of obtaining lower or discounted rates for M/S benefits but not for MH/SUD benefits, this demonstrates that the process of applying OON reimbursement rates is more favorable and less stringent for MH/SUD services compared to M/S services.

### In operation - data:

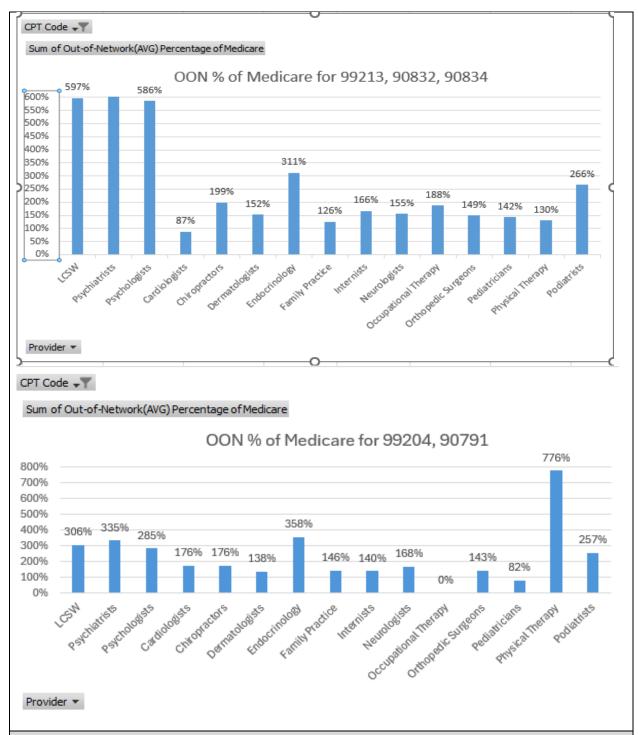
Zelis Claims Reimbursement edits demonstrates a total % of edits per claim of \$0.52 and 33% of total edits for MS and \$0.36 and 14% of total edits for MH/SUD. The average edit per claim is greater for MS than that of MHSUD and higher % of edits.

### Wellfleet Provider Reimbursement Rates, Out-Of-Network, Versus Medicare:

Wellfleet performed a comparison of average out of network claims payments during calendar year 2023 as a percentage of Medicare rates for the Wellfleet book of business for nine (9) CPT codes across three (3) MedSurg primary care physician types, five (5) MedSurg physician specialty types, four (4) MedSurg ancillary types and, one (1) MHSUD physician type, and two (2) MHSUD ancillary types. The results are as follows:

- 99203: There were insufficient MH/SUD 99203 claims except for psychologists resulting on 373% more than Medicare, whereas the MedSurg claims for 99203 were from 114% to 241% of Medicare. No concerning differences were noted.
- 99213, 90832 & 90834: MH/SUD psychiatrists, social workers and psychologists were reimbursed the most (> 500% of Medicare) vs. MedSurg PCPs (120-188% of Medicare) vs. MedSurg specialists (87%-311% of Medicare). The significant results for both M/S and MH/SUD show reimbursement substantially more for MHSUD.
- 99204 & 90791: MedSurg shows significant outlier of Physical Therapy at 776% of Medicare whereas the rest of MedSurg shows average of 140-358% of Medicare. MH/SUD significant results were both reimbursed >285% of Medicare. No concerning differences were noted.
- 99214, 90837 & 90830: MHSUD claims show a significant % of Medicare reimbursed more than that of MedSurg providers.





Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

 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

Wellfleet has the same policy and procedure for R&C payment of out-of-network claims for inpatient M/S and MH/SUD providers. There is no difference as written for R&C payment. In addition, Wellfleet applies a process to obtain discounted rates for M/S services through Zelis, but this process is not done for MH/SUD services and thus, MH/SUD services are treated less stringently. Therefore, in writing, the processes, standards, factors, and sources used to apply OON reimbursement to MH/SUD services is comparable and not more stringent than the processes, standards, factors, and sources used to apply OON reimbursement to M/S services.

The analysis of the 2023 claims reimbursement demonstrates the R&C payment versus Medicare rates for the same provider types and CPT codes did not provide concerns regarding possible issues with disparities in payment between similar types of MH/SUD versus M/S providers. Moreover, as demonstrated by the bar graphs, the OON reimbursement rates as a percentage of Medicare for MH/SUD providers are comparable or higher to the OON reimbursement rates as a percentage of Medicare for MedSurg providers, apart from physical therapists, who are a significant outlier for specified code groups for both in-network and out-of-network reimbursement. Therefore, in operation, the processes, standards, factors, and sources used to apply OON reimbursement to MH/SUD services is comparable and not more stringent than the processes, standards, factors, and sources used to apply OON reimbursement to M/S services. Wellfleet concludes that it applies R&C either equally or less stringently for MH/SUD providers than it does for M/S providers.

**Conclusion and Findings**: Both as written and in operation the processes, strategies, evidentiary standards, and other factors used to apply OON Reimbursement to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply OON Reimbursement to M/S benefits in the inpatient, outpatient, and emergency classifications. Therefore, the plan finds that the comparative analysis demonstrates its OON Reimbursement practices are compliant with MHPAEA.

## **NQTL: Formulary Design and Tiering**

### Classification(s): Prescription Drugs

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Formulary Design and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

### Provide a clear description of the specific NQTL, plan terms, and policies at issue:47

Formulary Design: Wellfleet uses a prescription drug formulary, which is a list of medications designed to manage prescription costs without affecting the quality of care by identifying and encouraging use of the most clinically effective and cost-effective medications. Formulary design refers to the process that the plan uses to develop the approved list of drugs covered under the pharmacy benefit plan. This is also called formulary placement. Drugs that are not on the formulary may be covered on an exception basis if they are excluded and if medical necessity can be established based on plan-approved prior authorization criteria or applicable regulations. Please see guideline named "Excluded Formulary Drug Exception" within the prior authorization guidelines on www.wellfleetrx.com/students/formularies.

Formulary Tiering: Formulary tiering refers to the placement of particular drug products on various cost-sharing tiers, ranging from 1 to 3.

Wellfleet uses the following formulary tiers:

- Tier 1 (preferred generics): Lowest copayment for select drugs that offer the greatest value compared to other drugs used to treat similar conditions.
- Tier 2 (non-preferred generics and preferred brands): Medium copayment covers brand name drugs that are generally more affordable or may be preferred compared to other drugs to treat the same conditions. This tier also covers non-preferred generic drugs.
- Tier 3 (non-preferred brands): High copayment covers higher cost brand name drugs. Specialty drugs fall under the same tiering structure but may subject to a specialty tier copay. Specialty drugs are pharmaceutical, biotech or biological drugs that are used in the management of chronic, orphan or rare diseases and have a monthly cost > \$670 for a 30-day supply. These injectable or non-injectable medications may possess more than one of the following attributes: Requires specialized storage, distribution, and/or handling; Frequent dosing adjustments and clinical monitoring to decrease potential for drug toxicity and improve clinical outcomes; Involves additional patient education, adherence, and/or support; May include generic or biosimilar products; and/or limited or exclusive drug distribution restrictions. These drugs are denoted on the formulary by "SP".

### Identify the Plan's formulary:48

Please see <a href="https://wellfleetrx.com/wp-content/uploads/2023/07/Wellfleet-Rx-Student-Formulary-July-2023.pdf">https://wellfleetrx.com/wp-content/uploads/2023/07/Wellfleet-Rx-Student-Formulary-July-2023.pdf</a>

Step 2 – Identify the factors used to determine how the Plans designs its formulary for mental health or substance use disorder and medical/ surgical drugs<sup>49</sup>

<sup>&</sup>lt;sup>47</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>48</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>49</sup> This section is responsive to Requirement 3 in FAQ Part 45 at 4.

### Medical/Surgical:

Factors for determining formulary placement and tiering include:

- 5. Availability of Cost-Effective alternatives
- 6. High variability in cost within drugs in a given therapeutic class
- 7. Member Impact (this factor is used only to determine when a negative shift in formulary placement or tiering should be applied)

#### MH/SUD:

Factors for determining formulary placement and tiering include:

Same as M/S

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Formulary Design to mental health or substance use disorder benefits and medical or surgical benefits.

### Medical/Surgical:

- Factor 1: Availability of Cost-Effective alternatives
  - Source: First Databank (FDB), FDA
     Prescribing Information, professionally recognized treatment guidelines, peer-reviewed medical literature
  - o Evidentiary Standard: Availability of alternate therapies (brand/generic). This is determined through discussions at P&T Committee meetings, that are based on therapeutic class reviews and new drug reviews. These are created using the sources above by Wellfleet's Clinical Pharmacist. These reviews contain information on indications, dosing & administration, clinical and comparative efficacy, clinical guidelines, contraindications & special populations. etc. The P&T Committee reviews clinical guidelines and nationally accepted standards of care to assess whether recommended alternative therapies exist. The P&T Committee discussions may determine that two or more drugs are expected to achieve clinically equivalent therapeutic outcomes. These discussions. along with the other factors listed in this section, guide the recommendations that are brought to the Value Assessment Committee for final determination on formulary status and tiering.

### MH/SUD:

Same as M/S

- Factor 2: High variability in cost within drugs in a given therapeutic class
  - Source: First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis.
  - Evidentiary Standard: High cost is defined as anything over \$670/month supply. Also taken into account are the availability of alternate therapies (brand/generic) & lowest total net cost for course of therapy for given conditions. If the drug is considered to have a high variability in cost, the VAC makes a recommendation for assignment to preferred or non-preferred tiers based on its evaluation of comparative net cost, comparing to other drugs in those tiers.
- Factor 3: Member Impact (this factor is used only to determine when a negative shift in formulary placement or tiering should be applied)
  - Source: Internal claims data, internal market and competitive analysis
  - Evidentiary Standard: The number of members that will be negatively impacted by either removing a drug product from formulary or shifting from 'preferred' tier to 'non-preferred'. This is only taken into account to decide not to apply a negative shift for members. If both factors 1 & 2 suggest removing a drug product from formulary or shifting from 'preferred' tier to 'non-preferred', but there would be a large member impact, we would put the interest of our members first and not make changes.

### Use of Factors - Formulary Design

For determining formulary design (i.e. inclusion on the formulary) the P&T committee first assesses the clinical efficacy and availability of cost effective alternative as described in Factor 1. Then, the Value Assessment Committee will assess the Cost as described in Factor 2 and makes a recommendation for final determination for inclusion on the formulary. In determining whether to remove a drug from the formulary, the VAC considers Factor 3 (in light of the committees analysis of Factors 1 and 2) for final determination.

### Use of Factors - Formulary Tiering

For determining formulary tiering (i.e. which tier a drug is assigned to on the formulary), the P&T committee assesses Factors 1 and 2 to determine where the drug should be assigned, and makes a recommendation to the Value Assessment Committee for final determination. If the committee is considering moving the drug to a higher-cost tier, then Factor 3 is considered (in light of the committee's findings on Factors 1 and 2) to determine whether member impact cuts against assigning that particular drug to a higher cost tier. A recommendation is then made by the the Value Assessment Committee for final approval.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

### Timelines/ frequency of review:

 Formulary design and tiering are analyzed semi-annually, unless otherwise prohibited by state law.

### Formulary Tiering Designation Process:

- The P&T Committee reviews all newly approved drugs and newly-approved indications and dosage forms for formulary status and recommendations for utilization management. The P&T Committee make recommendations for the final version of the formulary and related documents.
- The P&T Committee documents are presented to the health plan Value Assessment Committee (VAC). The VAC is tasked to maintain and approve recommended changes to the formulary, drug prior authorization

### Same as M/S

guidelines, and any programs/procedures that affect the utilization of drugs. For formulary decisions on drugs used to treat mental health or substance use disorders, the P&T Committee utilizes appropriate experience and knowledge in treating patients with the specific disease state. The P&T Committee has at least one member in the psychiatry specialty. VAC Committee meetings are held at least semi-annually. First the VAC committee reviews the P&T Committee recommendation, then the VAC Committee makes a final clinical decision.

- The VAC reviews the clinical decision and evaluates financial and operational impacts to make final determinations for formulary placement.
- Finally, this final formulary placement decision is reviewed by the health plan VAC committee to confirm alignment with clinical decisions.

### Formulary Design Management:

 Tiered drug formularies involve groupings of drugs subject to different levels of cost-sharing which are referred to as Tiers. The Student Formulary is a three-tier benefit design, where the member shares the cost of prescription drug therapy at three levels of copayment. In most instances, generically available drugs will be covered under the first or lowest copay tier, branded drugs listed on the Formulary will be covered under the second copay tier, and branded drugs not on the Formulary will be covered under the third or highest copay tier. Formulary Development & Maintenance Process (Role of P&T Committee):

- The process, strategies, and evidentiary standards used in applying Formulary Design and tiering are the same for both MH/SUD and M/S drugs, as written. The factors identified in Step Two and the sources identified in Step Three apply equally to MH/SUD and M/S drugs.
- Additionally, to become members of the P&T Committee, the physicians must be board certified licensed physicians or pharmacists with over 5 years of practicing in their respective fields. We use the clinical expertise of the P&T Committee members along with published clinical guidelines and scientific evidence to achieve consensus in order to set Formulary recommendations.
- As written, Formulary Design processes are the same for both M/S and MH/SUD drugs. The Formulary Management Policy is applied equally to both types of drugs and is reviewed annually for biased verbiage by the Director of Clinical Programs, Clinical Pharmacist, and Chief Medical Officer, and any updates required are made. The current formulary management policy states:
  - o "In order to comply with the Mental Health Parity and Addiction Equity Act (MHPAEA) and other applicable mental health parity laws, no aspect of the Formulary design, including tiering and UM decisions, shall be based on policies, processes, and operations that are more stringent for medications used to treat mental health conditions and substance use disorders (MH/SUD) as compared to medications used to treat medical or surgical conditions. At least annually, Wellfleet and [P&T Vendor] will complete analysis on the Non-

**Quantitative Treatment** Limitations (NQTLs) that apply to the Formulary, which includes identifying each NQTL. identifying the factors considered in the design of the NQTLs, identifying the sources used to define the factors considered in the design of the NQTLs, and analyzing whether the processes, strategies, and evidentiary standards used in applying the NQTLs are comparable and no more stringently applied to medications used to treat MH/SUD conditions as compared to medications used to treat medical or surgical conditions, as written and in operation."

## Role of the P&T Committee and VAC Committee:

- To become members of the P&T Committee, the physicians must be board certified licensed physicians with over 5 years of experience in their respective fields. P&T is made up of varying specialties that cover a wide range of diagnoses and care settings.
- The VAC is composed of internal leadership and key employees at Wellfleet. Membership covers the clinical & pharmacy team, finance team, sales team, and member experience team.
- The P&T committee determines include/exclude/optional formulary status based upon the evidentiary standards set forth in Step 3 without regard as to whether the drug is used to treat a medical condition or a MH/SUD condition. The Value Assessment Committee (VAC), considers the value of drugs by evaluating both factors set forth in Step 3, including net cost, market share, brand and generic

pipeline, drug utilization trends and cost effectiveness of clinically similar medications. Based on the recommendations of the P&T Committee, the VAC decides on formulary tiering. The processes, strategies, and evidentiary standards the VAC uses in Formulary Design for MH/SUD drugs are comparable to, and not more stringently applied than, the processes, strategies, and evidentiary standards used in tiering for M/S drugs. The P&T Charter and VAC charter are reviewed at least annually for parity. There is no language indicating a bias towards one classification of drugs of the other, and the same standards (as seen above) are used for both.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Formulary Design for M/S and MHSUD benefits in operation:

To ensure that the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for M/S drugs, we completed a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to each copay tier. See table below for M/S results.

Medical/Surgical	Tier	% of Total Number of Drugs
Υ	1	49.70%
Υ	2	17.18%
Υ	3	33.12%
Total		100%

 To ensure that the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for M/S drugs, we completed a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to each copay tier. See table below for MH/SUD results.

MHSU	Tier	% of Total Number of Drugs
Υ	- 1	68.80%
Υ	2	12.68%
Y	3	18.51%
Total		100%

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

As written: Wellfleet uses the same formulary tiering decision making process for M/S and MH/SUD drugs. On a semi-annual basis, drug formulary reviews go through multiple levels of clinical review from the P&T Committee initial evaluation and tiering recommendation to the VAC's final decision. The process is heavily clinically driven using the following factors: availability of cost-effective alternatives, high variability in cost within drugs in a given therapeutic class, and member impact. The sources used in assessing whether each factor has been met include First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines, peer-reviewed medical literature. Moreover, the sources and evidentiary standards used are the same regardless of the drug's MH/SUD or M/S status.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to MH/SUD drugs, <u>as written</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to M/S drugs.

In operation: In operation, cost-sharing is applied comparably and no more stringently to MH/SUD drugs relative to M/S drugs. We evaluate stringency in operation by analyzing the distribution of M/S and MH/SUD drugs across formulary tiers to ensure that tiering placements are not disproportionately favorable to M/S drugs. Tier 1 (preferred generics) includes a significantly higher percentage of MH/SUD drugs (68.80% of all formulary MH/SUD drugs) compared to M/S drugs (49.70% of all formulary M/S drugs). For Tier 2 (non-preferred generics and preferred brands), a lower percentage of formulary MH/SUD drugs are available (12.68%) compared to formulary M/S drugs (17.18%), however, the lower percentage of preferred brand MH/SUD drugs is explained by the disproportionately high rate of availability of MH/SUD generic drugs. Tier 3 (non-preferred brands) includes a significantly lower percentage of MH/SUD drugs (18.51% of all formulary MH/SUD drugs) compared to the percentage of M/S drugs (33.12% of all formulary M/S drugs).

Thus we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to MH/SUD drugs, *in operation*, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to M/S drugs.

**Conclusion**: Both as written and in operation the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to M/S benefits in the prescription drug classification. Therefore, the plan finds that the comparative analysis demonstrates its Formulary Design and Tiering practices are compliant with MHPAEA.

## **NQTL: Quantity Limits**

### Classification(s): Prescription Drugs

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Quantity Limits and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Provide a clear description of the specific NQTL, plan terms, and policies at issue:50

Quantity Limit is defined in the Wellfleet Rx Student Formulary as: "Coverage may be limited to specific quantities per prescription and/or time period."

Quantity Limits restrict the amount dispensed per Prescription Order or Refill and/or the amount dispensed per month's supply and are applied to ensure members receive clinically appropriate and medically necessary drugs.

Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Quantity Limit NQTL and the guidelines that drive the decisions by ESI are approved by Wellfleet's internal Pharmacy and Therapeutics Committee (P&T) and Value Assessment Committee (VAC). Quantity Limit is defined, in the Wellfleet Pharmacy and Therapeutics Committee Policy, as "Quantity Limit: A limitation on the amount dispensed per Prescription Order or Refill and/or the amount dispensed per month's supply".

## Identify the M/S drugs for which Quantity Limits are required:51

Identify the MH/SUD drugs for which Quantity Limits are required:52

Please see attached (Covered Services Attachment) which details benefits subject to QL Please see attached (Covered Services Attachment) which details benefits subject to QL

<sup>&</sup>lt;sup>50</sup> This section is responsive to Requirement 1 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>51</sup> This section is responsive to Requirement 2 in FAQ Part 45 at 4.

<sup>&</sup>lt;sup>52</sup> *Id*.

Step 2 – Identify the factors used to determine that Quantity Limits will apply to mental health or substance use disorder benefits and medical or surgical drugs<sup>53</sup>

### Medical/Surgical:

Factors for determining whether a prescription drug product will have Quantity Limit or not:

- 1. Safety
- 2. Anticipated excessive utilization
- 3. Member Impact

### MH/SUD:

Factors for determining whether a prescription drug product will have Quantity Limit or not:

1. Same as M/S

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Quantity Limits to mental health or substance use disorder benefits and medical or surgical benefits.

### Medical/Surgical:

- Factor 1: Safety This factor carries more weight due to the member safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  - o Source: FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care, nationally recognized Compendia Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peerreviewed medical literature.
  - Evidentiary Standard: P&T Committee members discuss safety of newly released

#### MH/SUD:

- Factor 1: Safety This factor carries more weight due to the member safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  - Source: FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as ASAM criteria or APA treatment guidelines, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.

<sup>&</sup>lt;sup>53</sup> This section is responsive to Requirement 3 in *FAQ Part 45* at 4.

products to determine if they have potential for unsafe use. Sources listed above are compiled by Wellfleet's Clinical Pharmacist into New Drug Reviews and Therapeutic Class Reviews. These reviews contain information on indications, dosing & administration, clinical and comparative efficacy, clinical guidelines, contraindications & special populations, etc. These are forwarded to the P&T committee prior to the meetings for their review. Meeting discussions include an analysis of: appropriate dosing, potential overdose, prescribing by particular specialty provider, adherence or potential non-adherence to quidelines, etc.

- Factor 2: Anticipated excessive utilization
  - Source: Aggregated data or non-identifiable utilization reports, FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.
  - Evidentiary Standard: Clinical Pharmacist reviews claims data every 6 months and compares actual utilization against the recommendations in the sources identified above (e.g. FDA prescribing information, dosing schedules, etc.) to determine whether a drug is being used excessively or inappropriately. "Excessive

 Evidentiary Standard: Same as M/S

- Factor 2: Anticipated excessive utilization
  - Source: Aggregated data or non-identifiable utilization reports, FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care such as ASAM criteria or APA treatment guidelines, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.
  - Evidentiary Standard: Same as M/S.

utilization" is defined as anything above the FDA approved dosing schedule or recommended dosage in peerreviewed medical journals. If the Clinical Pharmacist determines a drug is subject to potential excessive utilization, the Clinical Pharmacist or the P&T Committee may recommend applying a quantity limit to the Value Assessment Committee (VAC). The VAC reviews the Clinical Pharmacist's and the P&T Committee recommendation to approve the decision of applying such limmitation.

- Factor 3: Member Impact (this factor is used only to determine when QL should not be applied)
  - Source: Internal claims data, internal market and competitive analysis
  - Evidentiary Standard: The Value Assessment Committee reviews a cost report for the past year to determine the impact and number of members that maybe be using a particular benefit that is being considered for QL application. The VAC determines the number of members that will be negatively impacted by quantity limit additions. The VAC makes a decision based on their professional judgement as to whether QL should not be applied to avoid negative member impact. This is only taken into account to decide not to apply or to remove a quantity limit requirement from a medication and is not used in the application process for QL. If factors 1 and 2 suggest the
- Factor 3: Member Impact (this factor is used only to determine when QL should not be applied)
  - Source: Internal claims data, internal market and competitive analysis
  - Evidentiary Standard: Same as M/S

addition of QL, but we anticipate significant member or client impact based on our covered demographic, we may put the interest of our members first and not assign a QL designation.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

Timelines and deadlines, frequency of review:

- Turnaround times for review and either approving or denying a QL exception request are based on state requirements. However, on average across Wellfleet's book of business QL exception requests are processed within 1 business day.
- Authorizations for both M/S and MHSUD drugs are valid for 365 days from approval. Approvals may be for a shorter duration if the FDA labeling guidelines have strict duration of therapy limits or monitoring requirements after initiation. Other exceptions are for products that have regulatory implications, which will be approved based on the regulatory statute.
- Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance.

Forms and/or other information required to be submitted by the provider:

 Providers can request Quantity Limit Exceptions by calling Express Scripts Prior Authorization department Timelines and deadlines, frequency of review:

Same as M/S

Forms and/or other information required to be submitted by the provider.

Same as M/S

directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a Prior Authorization Request Form and faxing directly to Express Scripts Prior Authorization department.

Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination:

The P&T Policy & Procedures and Formulary Management Policy are reviewed by Wellfleet's Chief Medical Officer, Director of Clinical Programs, and Clinical Pharmacist, at least annually to ensure there is no verbiage indicating a bias towards any particular subset of drugs. These policies dictate that all decisions should be based off of the clinical merits of the drug, not the classification of drug itself. Quantity Limit is imposed on drug products based on the factors presented previously for both classifications of drugs. In the review of the P&T policy, it is stated that "The clinical decisions made by the P&T Committee are based on sound scientific evidence and standards of practice that include: 1. Assessing peer-reviewed medical literature. 2. Referencing published practice guidelines. 3. Comparing efficacy, side effects, and potential drug interactions among alternative drug therapies. 4. Assessing impact of formulary decisions to patient compliance." There is also the presence of a non-discriminatory section, stating that members shall not "discriminate based on age, disability, race, ethnicity, gender, sexual orientation, or health status." Members non-adhering to either of these statements will be recused from the committee. No recusals have been a result of non-adherence to these policies.

Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination:

Same as M/S

Relevant Decision Making Committees

Same as M/S

### Relevant Decision Making Committees

- P&T Committee
  - The P&T Committee is responsible for assessing the clinical merits of drug therapies. The committee shall provide clinical rationale and guidance on appropriate quantities/dosing. The Value Assessment Committee (VAC) follows the P&T Committee recommendations to finalize any quantity limit decisions.
  - The P&T Committee is responsible for approving any new Utilization Management policies (guidelines) or negative changes (any change creating a larger barrier to member access) to these guidelines. If a guideline change includes any criteria that differs from the FDA approved labeling information, it will also require justification and approval from the P&T Committee. Guidelines shall also be reviewed annually for approval. At each P&T meeting, the new, updated, and a quarter of all other guidelines will be discussed and approved/denied.
- Value Assessment Committee (VAC)
  - The VAC is responsible for determining tiering and Utilization Management decisions for drugs that are designated as 'include' by the P&T Committee. These drugs shall not be removed from formulary without prior approval from the P&T Committee. Also, determining coverage, tiering, and Utilization Management decisions for drugs that are

designated as 'optional' by the P&T Committee. The VAC shall use clinical notes from P&T, along with other sources listed above, to make quantity limit determinations.

#### Minimum qualifications for reviewers:

- To become members of the P&T Committee, the physicians must be board certified licensed physicians with over 5 years of experience in their respective fields. We use the clinical expertise of the P&T Committee members along with published clinical guidelines and scientific evidence to achieve consensus in order to set Quantity Limits.
- Every PAR, UMP, Nurse, and Medical Director goes through extensive training to make sure we are providing the most complete and comprehensive service for each one of our members. The training consists of both in classroom, on the job shadowing, monthly quality reviewing of cases, and weekly meetings to provide any new/updated information that needs to be shared with the teams.

#### Minimum standards to issue a denial:

• If a prescription exceeds the designated quantity limit, the filling pharmacy will be issued a denial. If the member and provider elect to request an exception, they will be asked to submit documentation in support of use of the product. The exact process can be seen in Wellfleet's PA guideline packet at www.Wellfleetrx.com/formularies. This process is the same for both M/S and MH/SUD drugs.

#### Minimum qualifications for reviewers:

Same as M/S

Minimum standards to issue a denial:

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Quantity Limits for M/S benefits and MHSUD benefits:

To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply quantity limit to M/S drugs, QL for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to a quantity limit. See table below for M/S results.

To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply quantity limit to M/S drugs, QL for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to a quantity limit. See table below for MH/SUD results.

M/S QL Requirements	
Total M/S Drugs	8,742
Total M/S Drugs Requiring QL	1,712
QL Required Rate	20%

MH/SUD QL Requirements	
Total MH/SUD Drugs	772
Total MH/SUD Drugs Requiring QL	285
QL Required Rate	37%

- We also completed an analysis of the turnaround times for QL exception requests to be issued either an approval or denial. On average, the turnaround time for M/S drugs was less than 1 day
- We also completed an analysis of denial rates for requests for quantity limit exceptions in calendar year 2021. Results can be seen in the table below.

Although the percentage of MH/SUD drugs is slightly higher than the M/S drugs, the selection process of drugs for the QL NQTL are still considered comparable to that for M/S drugs. The factors and sources used are the same for both MH/SUD and M/S drugs. One reason for the higher percentage seen in the MH/SUD drugs is due to safety concerns.
 MH/SUD drugs can have serious side effects, and many have potential for

Global M/S QL Analysis	
Total QL	431
Requests	431
Total QL	275
Approvals	2/3
Total QL Denials	156
QL Approval Rate	63.8%
QL Denial Rate	36.2%

MD M/S QL Analysis	
Total QL	2
Requests	2
Total QL	2
Approvals	2
Total QL Denials	0
QL Approval Rate	100%
QL Denial Rate	0%

abuse, so quantity limits would help ensure patients are not taking more than what is approved by the FDA. Some drugs in the M/S class have similar concerns, but since the M/S category is so broad, it is a much smaller percentage compared to the MH/SUD category. There are also many more subcategories within the M/S class compared to the MH/SUD class of drugs. Many of those subcategories do not or rarely have traditionally have Quantity Limit edits (i.e. Allergenic Extracts, Antidotes, Detergents, Diagnostic Agents, etc.).

- We also completed an analysis of the turnaround times for QL exception requests to be issued either an approval or denial. On average, the turnaround time for MH/SUD drugs was less than 1 day
- We also completed an analysis of denial rates for requests for quantity limit exceptions in calendar year 2021. Results can be seen in the table below.

Global MH/SUD QL Analysis	
Total QL Requests	260
Total QL	119
Approvals	119
Total QL Denials	141
QL Approval Rate	46%
QL Denial Rate	54%

MD MH/SUD QL Analysis	
Total QL	1
Requests	I
Total QL	1
Approvals	I
Total QL Denials	0
QL Approval Rate	100%
QL Denial Rate	0%

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

As written: The process for creating quantity limits for a drug is the same for both M/S and MH/SUD drugs. The P&T Policy & Procedures and Formulary Management Policy are reviewed by Wellfleet's Chief Medical Officer, Director of Clinical Programs, and Clinical Pharmacist, at least annually to ensure there is no verbiage indicating a bias towards any particular subset of drugs. These policies dictate that all decisions should be based off of the clinical merits of the drug, not the classification of drug itself. Quantity limit is imposed on drug products based on the factors presented previously for both classifications of drugs.

Whether to recommend a quantity limit for a drug is based on the drug's safety, anticipated excessive utilization, and member Impact. Whether each factor is met is based upon FDA Prescribing Information, professionally recognized treatment guidelines used to define clinically appropriate standards of care, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), peer-reviewed medical literature, aggregated data or non-identifiable utilization reports, internal claims data, internal market and competitive analysis. The factors, standards and sources for those standards are the same regardless of whether a drug is a M/S or MH/SUD drug.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Quantity Limits to MH/SUD drugs, <u>as written</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Quantity Limits to M/S drugs.

Moreover, a request for quantity limits is subject to the same review process for both M/S and MH/SUD drugs, and the same reviewers are used for M/S and MH/SUD drug authorization reviews. Authorizations for both M/S and MHSUD drugs are valid for 365 days from approval. Approvals may be for a shorter duration if the FDA labeling guidelines have strict duration of therapy limits or monitoring requirements after initiation. Other exceptions are for products that have regulatory implications, which will be approved based on the regulatory statute. Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance

In Operation: In operation, the percentage of MH/SUD drugs with approved quantity limits is lower than the percentage of M/S drugs requiring with approved quantity limits. The denial rate for MH/SUD drug requests (0%) is the same as the denial rate for M/S drug requests (0%). One reason for the potential for higher denial percentage seen in the MH/SUD drugs is due to safety concerns. MH/SUD drugs can have serious side effects, and many have potential for abuse, so quantity limits would help ensure patients are not taking more than what is approved by the FDA. Some drugs in the M/S class have similar concerns, but since the M/S category is so broad, it is a much smaller percentage compared to the MH/SUD category. There are also many more subcategories within the M/S class compared to the MH/SUD class of drugs. Many of those subcategories do not or rarely have traditionally have Quantity Limit edits (i.e. Allergenic Extracts, Antidotes, Detergents, Diagnostic Agents, etc.). Wellfleet reviewed the data and associated claims and determined that the application of

quantity limits and denial rates were clinically appropriate subject to the factors, sources, and evidentiary standards identified in Step 3. Moreover, federal parity guidance is clear that metrics alone are not indicative of parity non-compliance so long as the plan has investigated the data, the reasons for the underlying data, and has determined that the same processes, strategies, factors and evidentiary standards were applied to MH/SUD and M/S drugs. Wellfleet has done so here, and has determined MH/SUD and M/S drugs were treated comparably.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply quantity limits to MH/SUD drugs, <u>in operation</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply quantity limits to M/S drugs.

**Conclusion**: Both as written and in operation the processes, strategies, evidentiary standards, and other factors used to apply Quantity Limits to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Quantity Limits to M/S benefits in the prescription drug classification. Therefore, the plan finds that the comparative analysis demonstrates its Quantity Limits practices are compliant with MHPAEA.

# **NQTL: Step Therapy**

## Classification(s): Prescription Drugs

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Step Therapy and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification

Provide a clear description of the specific NQTL, plan terms, and policies at issue:54

From Wellfleet's standard Certificate of Coverage Template: Step therapy (ST) is a process in which the Member may need to use one (1) or more types of Prescription Drug before We will Cover another as Medically Necessary. A "step therapy protocol" means Our policy, protocol or program that establishes the sequence in which We approve Prescription Drugs for a Member's medical condition.

Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Step Therapy NQTL and the guidelines that drive the decisions by ESI are

<sup>&</sup>lt;sup>54</sup> This section is responsive to Requirement 1 in *FAQ Part 45* at 4.

approved by Wellfleet's internal Pharmacy and Therapeutics Committee (P&T) and Value Assessment Committee (VAC).

Step Therapy is defined, in the Wellfleet Pharmacy and Therapeutics Committee Policy, as "Step Therapy: A process in which the member may need to use one (1) or more types of Prescription Drug before coverage of a second Prescription Drug."

# Identify the M/S drugs for which Step Therapy is required:55

Please see attached (Covered Services Attachment) which details benefits subject to ST

# Identify the MH/SUD drugs for which Step Therapy is required:<sup>56</sup>

Please see attached (Covered Services Attachment) which details benefits subject to ST

# Step 2 – Identify the factors used to determine that Step Therapy will apply to mental health or substance use disorder benefits and medical or surgical drugs<sup>57</sup>

#### Medical/Surgical:

Factors for determining whether a prescription drug product will have Step therapy or not:

- 8. High variability in cost within drugs in a given therapeutic class
- Availability of Cost-Effective alternatives
- Member Impact (this factor is used only to determine when ST should not be applied)

#### MH/SUD:

Factors for determining whether a prescription drug product will have Prior Authorization or not:

<sup>&</sup>lt;sup>55</sup> This section is responsive to Requirement 2 in *FAQ Part 45* at 4.

<sup>&</sup>lt;sup>56</sup> *Id* 

<sup>&</sup>lt;sup>57</sup> This section is responsive to Requirement 3 in FAQ Part 45 at 4.

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Step Therapy to mental health or substance use disorder benefits and medical or surgical benefits.

#### Medical/Surgical:

# MH/SUD:

Factor 1: High variability in cost within drugs in a given therapeutic class

herapeutic class

Source: First Databank

(FDB), internal market and competitive analysis, therapeutic class total net cost analysis.

Evidentiary Standard: High cost is defined as \$670/month supply Also taken into account are the availability of alternate therapies (brand/generic) & lowest total net cost for course of therapy for given conditions.

Factor 2: Availability of Cost-Effective alternatives

- Source: First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines, peer-reviewed medical literature
- Evidentiary Standard: Availability of alternate therapies (brand/generic). This is determined thorough discussions at P&T Committee meetings, that are based on therapeutic class reviews and new drug reviews. These are created using the sources above by Wellfleet's Clinical Pharmacist. These reviews contain information on indications, dosing & administration, clinical and comparative efficacy, clinical guidelines, contraindications &

special populations, etc. The P&T Committee reviews clinical guidelines and nationally accepted standards of care to assess whether recommended alternative therapies exist. These discussions, along with the other factors listed in this section, guide the recommendations that are brought to the Value Assessment Committee for final determination on ST.

Factor 3: Member Impact (this factor is used only to determine when ST should not be applied)

- Source: Internal claims data, internal market and competitive analysis
- Evidentiary Standard: The number of members that will be negatively impacted by step therapy additions. This is only taken into account to decide not to apply or to remove a step therapy requirement from a medication and is not used in the application process for step therapy. If both factors 1 & 2 suggest the addition of step therapy, but we anticipate significant member or client impact based on our covered demographic, we would put the interest of our members first and not assign a step therapy designation.

The Value Assessment Committee considers factors 1 & 2 equally in order to make a determination as to whether Step Therapy should be applied. If both factors 1 & 2 are met, the VAC considers Factor 3 (member impact) to assess whether Step therapy

should be applied in light of anticipated member impact.

Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

Briefly describe the processes by which Step Therapy is applied to M/S benefits:

Timelines and deadlines, frequency of review:

- Turnaround times for review and either approving or denying a ST request are based on state requirements. However, on average across Wellfleet's book of business ST requests are processed within 1 business day.
- Authorizations across the board for both M/S and MHSUD drugs are valid for 365 days from approval. The only exceptions here are for products that have regulatory implications, which will be approved based on the regulatory statute.
- Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance.

Forms and/or other information required to be submitted by the provider:

 Providers can request Step Therapy Exceptions by calling Express Scripts Prior Authorization department directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a standard Briefly describe the processes by which Step Therapy is applied to MH/SUD benefits:

Timelines and deadlines, frequency of review:

Same as M/S

Forms and/or other information required to be submitted by the provider.

Prior Authorization Request Form and faxing directly to Express Scripts Prior Authorization department. Submission of medical chart notes / patient drug history may be required for these Step Therapy Exceptions.

 If a member has a history of the required step drugs in their profile with Express Scripts, they will automatically get a paid claim at point-of-sale without the provider being required to submit an exception request. This can be done for all drugs that require Step Therapy, regardless of drug classification.

Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination:

 The P&T Policy & Procedures and Formulary Management Policy are reviewed at least annually to ensure there is no verbiage indicating a bias towards any particular subset of drugs. These policies dictate that all decisions should be based off the clinical merits of the drug, not the classification of drug itself.

Relevant Decision Making Committees

- P&T Committee
  - The P&T Committee is responsible for assessing the clinical merits of drug therapies. The committee shall provide clinical rationale and guidance on formulary placement. The Value Assessment Committee (VAC) follows the P&T Committee recommendations to finalize formulary placement decisions.
  - The P&T Committee is responsible for approving any

Utilization management manuals and any other documentation of UM processes that are relied upon to make a determination:

Same as M/S

Relevant Decision Making Committees

new Utilization Management policies (guidelines) or negative changes (any change creating a larger barrier to member access) to these quidelines. If a quideline change includes any criteria that differs from the FDA approved labeling information, it will also require justification and approval from the P&T Committee. Guidelines shall also be reviewed annually for approval. At each P&T meeting, the new, updated, and a quarter of all other guidelines will be discussed and approved/denied.

- Value Assessment Committee (VAC)
  - The VAC is responsible for determining tiering and Utilization Management decisions for drugs that are designed as 'include' by the P&T Committee. These drugs shall not be removed from formulary without prior approval from the P&T Committee. Also, determining coverage, tiering, and Utilization Management decisions for drugs that are designated as 'optional' by the P&T Committee.

#### Minimum qualifications for reviewers:

 To become members of the P&T Committee, the physicians must be board certified licensed physicians with over 5 years of experience in their respective fields. We use the clinical expertise of the P&T Committee members along with published clinical guidelines and scientific evidence to achieve consensus in order to set Quantity Limits.

#### Minimum qualifications for reviewers:

 [Need to get from ESI, but I believe it would be the same as M/S]  Every PAR, UMP, Nurse, and Medical Director goes through extensive training to make sure we are providing the most complete and comprehensive service for each one of our members. The training consists of both in classroom, on the job shadowing, monthly quality reviewing of cases, and weekly meetings to provide any new/updated information that needs to be shared with the teams.

Minimum standards to issue a denial:

- The same Exceptions policy, which is reviewed annually by the Pharmacy & Therapeutics Committee, is used for both MH/SUD and M/S drugs. It is also reviewed in order to determine whether there is any verbiage that would cause decisions regarding exceptions to the application of step therapy to be made out of parity. The exceptions policy currently requires one of four main points for approval, none of which are biased toward M/S or MH/SUD drugs: 1. The patient has a contraindication to the required Step drug; 2. The prescriber suspects the required Step drug to be ineffective for the patient; 3. The patient has tried a therapeutically equivalent dose of the required Step drug under the current or previous health plan for a long enough period of time to reach a therapeutic improvement and was discontinued due to lack of improvement; 4. The patient is currently receiving a positive outcome on the requested drug and should not discontinue.
- If a member has not met criteria for Step therapy exception and provider cannot provide documentation as described above for an exception, they will be issued a denial

Minimum standards to issue a denial:

 Depending on state requirements, a denial may only be issued by certain individuals with particular qualifications (e.g. physician with same/similar specialty licensed in same state, pharmacist, etc.). This is kept consistent for M/S and MH/SUD.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Step Therapy for M/S benefits and MH/SUD benefits:

To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply step therapy to M/S drugs, step therapy for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to step therapy. See table below for M/S results.

M/S ST Requirements	
Total M/S Drugs	8,742
Total M/S Drugs Requiring ST	285
ST Required Rate	3.3%

 We also completed an analysis of the turnaround times for ST requests to be issued either an approval or denial. To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply step therapy to M/S drugs, step therapy for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to step therapy. See table below for M/S results.

MH/SUD ST Requirements	
Total MH/SUD Drugs	772
Total MH/SUD Drugs Requiring ST	63
ST Required Rate	8.1%

 We also completed an analysis of the turnaround times for ST requests to be issued either an approval or denial. On average, the turnaround time for MH/SUD drugs was less than 1 day. On average, the turnaround time for M/S drugs was less than 1 day.

 We also completed an analysis of denial rates for requests for Step Therapy in calendar year 2022. Results can be seen in the table below.

Global M/S ST Analysis	
Total ST	7 11 141 19010
Requests	900
Total ST	
Approvals	807
	93
Total ST Denials	
ST Approval Rate	89.7%
ST Denial Rate	10.3%

MD M/S ST Analysis	
Total ST Requests	2
Total ST	2
Approvals	2
Total ST Denials	0
ST Approval Rate	100%
ST Denial Rate	0%

 We also completed an analysis of denial rates for requests for Step Therapy in calendar year 2022. Results can be seen in the table below.

Global MH/SUD ST Analysis	
Total ST Requests	287
Total ST	270
Approvals	270
Total ST Denials	17
ST Approval Rate	94%
ST Denial Rate	6%

MD MH/SUD ST Analysis	
Total ST Requests	1
Total ST	1
Approvals	I
Total ST Denials	0
ST Approval Rate	100%
ST Denial Rate	0%

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section

As Written: The process for creating a step therapy policy for a drug is the same for both M/S and MH/SUD drugs. Providers can request Step Therapy Exceptions by calling Express Scripts Prior Authorization department directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a standard Prior Authorization Request Form and faxing directly to Express Scripts Prior Authorization department. Submission of medical chart notes / patient drug history may be required for these Step Therapy Exceptions. Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Step Therapy NQTL and the guidelines that drive the decisions by ESI are approved by Wellfleet's internal Pharmacy and Therapeutics Committee (P&T) and Value Assessment Committee (VAC). They are reviewed by the P&T Committee, and ultimately subject to approval by the VAC Committee on an annual basis.

Whether to recommend a step therapy policy for a drug is based on three factors: 1) high variability in cost within drugs in a given therapeutic class, 2) availability of cost-effective alternatives, and 3) member impact. These factors are based on First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis, FDA prescribing information, professionally recognized treatment guidelines, peer-reviewed medical literature, internal claims data, internal market and competitive analysis. These

factors, standards and sources are the same regardless of whether a drug is a M/S or MH/SUD drug.

Thus we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Step Therapy to MH/SUD drugs, <u>as written</u>, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Step Therapy to M/S drugs.

In Operation: In operation, for both M/S and MH/SUD drugs, authorization approval rates are highly similar, and timelines adhere to NCQA and state standards. Finally, the percentage of MH/SUD drugs subject to Step Therapy (8.1%) is slightly higher than the percentage of M/S drugs subject to Step Therapy (3.3%), though a fewer number of MH/SUD drugs require Step Therapy (772) vs M/S drugs (8742) and, overall, very few drugs in general require Step Therapy (63/772 MH/SUD and 285/8742 M/S drugs require Step Therapy). The data demonstrates that the same percentage of step therapy requests are approved for MH/SUD drugs. Therefore, MH/SUD drugs are not being treated more stringently compared to M/S drugs.

Thus we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Step Therapy to MH/SUD drugs, *in operation*, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Step Therapy to M/S drugs.

**Conclusion**: Wellfleet has determined that step therapy is applied for MH/SUD drugs in a manner that is comparable to and no more stringent than that of M/S drugs, both as written and in operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose step therapy.

#### **Emergency Services**

Emergency Services does not impact the scope of care, treatment or benefits delivered to MH/SUD services and does not function as an NQTL under the parity requirements.

#### **Case Management**

Case Management does not impact the scope of care, treatment or benefits delivered to MH/SUD services and does not function as an NQTL under the parity requirements.

Wellfleet provides voluntary case management services which includes providing educational

information, assessment/evaluation, planning, facilitation, care coordination, discharge planning and other services to meet an individual's and family's comprehensive health care needs.

Participation in case management services is not required, and an enrollee's participation in case

management services does not limit the scope or duration of benefits for either MH/SUD or M/S

benefits. Consequently, case management does not function as an NQTL under the cited parity requirements.

MHPAEA Data Report for Calendar Year Ending December 31, 2023 (§15–144(f))							
Health Plan		McDaniel College Washington College St Johns College					
Benefit	Classificati on	# of Authorizati on Requests Received	# of Authorization Requests Approved	# of Authorization Requests Denied	% Approved	% Denied	
Mental Health Benefits	INN- Inpatient	132	132	0	100%	0%	
	OON- Inpatient	8	8	0	100%	0%	
	Emergency Services	4	4	0	100%	0%	
	RX	0	0	0	#DIV/0!	#DIV/0!	
	INN- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!	
	OON- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!	
Substanc e Use Disorder Benefits	INN- Outpatient- AllOther	3	2	1	67%	33%	
	OON- Outpatient- AllOther	0	0	0	#DIV/0!	#DIV/0!	
	INN- Inpatient	14	12	2	86%	14%	
	OON- Inpatient	3	3	0	100%	0%	

	Emergency Services	0	0	0	#DIV/0!	#DIV/0!
	RX	0	0	0	#DIV/0!	#DIV/0!
	INN- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!
	OON- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!
	INN- Outpatient- AllOther	0	0	0	#DIV/0!	#DIV/0!
	OON- Outpatient- AllOther	0	0	0	#DIV/0!	#DIV/0!
Medical /Surgical Benefits	INN- Inpatient	127	100	27	79%	21%
2333	OON- Inpatient	1	0	1	0%	100%
	Emergency Services	4	4	0	100%	0%
	RX	2	2	0		
	INN- Outpatient- Office	0	0	0	100%	0%
	OON- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!
	INN- Outpatient- AllOther	127	96	31	#DIV/0!	#DIV/0!
	OON- Outpatient- AllOther	5	3	2	76%	24%
Benefit	Classificati on	# of Claims Submitted	# of Claims Approved	# of Claims Denied	60% % Approved	40% % Denied
Mental Health Benefits	INN- Inpatient	114	61	53	E 407	A 1 07
Denienia	OON- Inpatient	0	0	0	54% #DIV/0!	46% #DIV/0!
					1101170:	11 01 7 0:

	Emergency Services	36	34	2	94%	6%
	RX	726	453	273	62%	38%
	INN- Outpatient- Office	370	349	21	94%	6%
	OON- Outpatient- Office	56	56	0	100%	0%
	INN- Outpatient- AllOther	69	61	8	88%	12%
	OON- Outpatient- AllOther	9	4	5	44%	56%
Substanc e Use Disorder Benefits	INN- Inpatient	0	0	0	#DIV/0!	#DIV/0!
	OON- Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	12	11	1	92%	8%
	RX	0	0	0	#DIV/0!	#DIV/0!
	INN- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!
	OON- Outpatient- Office	0	0	0	#DIV/0!	#DIV/0!
	INN- Outpatient- AllOther	0	0	0	#DIV/0!	#DIV/0!
	OON- Outpatient- AllOther	0	0	0	#DIV/0!	#DIV/0!
Medical /Surgical Benefits	INN- Inpatient	0	0	0	#DIV/0!	#DIV/0!
	OON- Inpatient	0	0	0	#DIV/0!	#DIV/0!
	Emergency Services	0	0	0	#DIV/0!	#DIV/0!

RX	937	575	362	61%	39%
INN- Outpatient- Office	196	196	0	100%	0%
OON- Outpatient- Office	6	6	0	100%	0%
INN- Outpatient- AllOther	16	16	0	100%	0%
OON- Outpatient- AllOther	0	0	0	#DIV/0!	#DIV/0!
					·