NQTL: EXPERIMENTAL, INVESTIGATIONAL, UNPROVEN

Classification(s): Inpatient In-Network & Out-Of-Network, Outpatient Office In-Network & Out-of-Network, Outpatient All Other In-Network & Out-of-Network, Emergency In Network & Out of Network, Pharmacy

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:
Wellfleet delegates its non-Pharmacy Utilization Management to Hines and Associates(Hines) and Advanced Medical Review(AMR) for True Choice plans.
Wellfleet definition of experimental, investigational and unproven is the same for M/S and MH/SUD.

Wellfleet defines Experimental and Investigational in its plan documents as services are medical procedures, equipment, medications, and cosmetic procedures that are not Medically Necessary and are not covered. These services are considered experimental and investigational if they meet any of the following criteria:

- The service does not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body.
- There is insufficient or inconclusive medical and scientific evidence to evaluate the service's therapeutic value.
- The service is not Medically Necessary and there is a safe and medically accepted alternative available.
- The service is a medical device established by the FDA as Category A, which are generally not covered because their safety and effectiveness have not yet been established.

Wellfleet delegates the act of Utilization Review for pharmacy benefits to Express Scripts (ESI). In the context of pharmacy benefits, EIU is defined as any drug product being utilized for an indication that is not either

1. FDA approved
   OR
2. has two studies in major peer-reviewed journals showing benefit OR 3. included in the diagnosis' clinical practice guidelines as a recommendation.

Identify the M/S benefits/services for which Prior Authorization is required:	***Identify the MH/SUD benefits/services for which Prior Authorization is required***:
The evaluation of Experimental, Investigational and Unproven (EIU) services are applicable to all M/S and MH/SUD services, regardless of benefit classification.	The evaluation of Experimental, Investigational and Unproven (EIU) services are applicable to all M/S and MH/SUD services, regardless of benefit classification.

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

Medical/Surgical:	**MH/SUD**:
FACTORS	**FACTORS**
1. 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;	1. 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;

2. 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; 3. The subject of review or approval by an Institutional Review Board for the proposed use except as provided in a clinical trial 4. The subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials. **For Prescription Drugs Only:** **Medical/Surgical:** **FACTORS** 1. FDA Approval 2. Inclusion in Peer Reviewed Medical Journals 3. Inclusion in Peer Reviewed Clinical Practice Guidelines	2. 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; 3. The subject of review or approval by an Institutional Review Board for the proposed use except as provided in a clinical trial 4. The subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials. **For Prescription Drugs Only:** **MH/SUD** **FACTORS** 1. FDA Approval 2. Inclusion in Peer Reviewed Medical Journals 3. Inclusion in Peer Reviewed Clinical Practice 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 E/I/U 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: 1. **Factor 1**: 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; **SOURCE**: Clinical Literature & FDA **Evidentiary Standard**: 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 sufficient evidence based proven relationship between the intervention and improved health outcomes. 2. **Factor 2:** 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; **SOURCE**: FDA approval or clearance is necessary along with evidence based clinical literature for physician review **Evidentiary Standards**: FDA published randomized controlled trials 3. **Factor 3:** The subject of review or approval by an Institutional Review Board for the proposed use except as provided in a clinical trial **SOURCE**: FDA approval or clearance is necessary but not sufficient for all diseases. **Evidentiary Standards**: National accreditation standards and internal studies on quality standards 4. **Factor 4:** The subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials.	**MH/SUD**: 1. **Factor 1**: 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; **SOURCE:** Clinical Literature & FDA **Evidentiary Standard:** 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 sufficient evidence based proven relationship between the intervention and improved health outcomes. 2. **Factor 2:** 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; **SOURCE:** FDA approval or clearance is necessary along with evidence based clinical literature for physician review **Evidentiary Standards:** FDA published randomized controlled trials 3. **Factor 3:** The subject of review or approval by an Institutional Review Board for the proposed use except as provided in a clinical trial **SOURCE**: FDA approval or clearance is necessary but not sufficient for all diseases **Evidentiary Standards**: National accreditation standards and internal studies on quality standards 4. **Factor 4**: The subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials.

SOURCE: 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 Standards:** Published randomized control trials **For Prescription Drugs Only:** **M/S** 1. **Factor 1:** FDA Approval **SOURCE**: FDA labeling language found in the "Drugs@FDA" Portal of the FDA's website (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm) **Evidentiary Standard**: Requested Diagnosis being included in the FDA approved labeling language 2. **Factor 2:** Inclusion in Peer Reviewed Medical Journals **SOURCE:** PubMed on the NIH database **Evidentiary Standard**: Requested Diagnosis being included in **two** separate peer reviewed clinical trials, studies, or articles associated with the requested diagnosis 3. **Factor 3:** Inclusion in Peer Reviewed Clinical Practice Guidelines **SOURCE**: PubMed on the NIH database **Evidentiary Standard**: Requested Diagnosis being included in **one** peer reviewed clinical practice guideline associated with the requested diagnosis	**SOURCE:** 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 Standards:** Published randomized control trials **For Prescription Drugs Only:** **MH/SUD** 1. **Factor 1:** FDA Approval **SOURCE**: FDA labeling language found in the "Drugs@FDA" Portal of the FDA's website (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm) **Evidentiary Standard**: Requested Diagnosis being included in the FDA approved labeling language 2. **Factor 2:** Inclusion in Peer Reviewed Medical Journals **SOURCE:** PubMed on the NIH database **Evidentiary Standard**: Requested Diagnosis being included in **two** separate peer reviewed clinical trials, studies, or articles associated with the requested diagnosis 3. **Factor 3:** Inclusion in Peer Reviewed Clinical Practice Guidelines **SOURCE**: PubMed on the NIH database **Evidentiary Standard**: Requested Diagnosis being included in **one** peer reviewed clinical practice guideline associated with the requested diagnosis
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.*	
For Medical/Surgical Benefits- Wellfleet's definition of experimental, investigational or unproven(E/I/U) is supplied in each plan document. Wellfleet delegates its utilization management to Hines and AMR in which Wellfleet definition of E/I/U is utilized. The Utilization Review Organizations hold accreditations in utilization review and subjects its agents to inter reliability ratio testing. Each delegate has subject matter experts that review the service and benefit under review as it applies to (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 including	For Medical/Surgical Benefits- Wellfleet's definition of experimental, investigational or unproven(E/I/U) is supplied in each plan document. Wellfleet delegates its utilization management to Hines and AMR in which Wellfleet definition of E/I/U is utilized. The Utilization Review Organizations hold accreditations in utilization review and subjects its agents to inter reliability ratio testing. Each delegate has subject matter experts that review the service and benefit under review as it applies to (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 including

• Randomized Controlled Trials (RCT), • randomized, blinded, placebo- controlled clinical systematic reviews, • observational, descriptive and panel studies that are non-experimental, and • professional recommendations based upon valid assessment of the available literature. For Prescription Drug Benefits - Experimental, Investigational, and Unproven only is applicable to medications that are either 1) Non-Formulary OR 2) require Prior Authorization. • The same Non-Formulary Exceptions policy is used for all medication classifications to provide appropriate E/I overrides of formulary status. This policy, entitled 'Excluded Formulary Drug Exception Criteria', is reviewed at least annually by the Pharmacy and Therapeutics Committee and approved. An annual audit is also conducted to ensure that the policy does not have differences in intent between classifications of medications. To date, no instances of verbiage that would require or insinuate discriminatory practices towards MH/SUD medications have been found, as the requirements are the same across the board for all non-formulary medications. The most recent audit found that the exception policy is the same for all classifications, and requires the following information to be granted approval: o Product being requested for either an **FDA approved indication** or an indication that is **considered safe and effective for the diagnosis by peer-reviewed medical literature or standards of medical practice** o Patient has met one of the following: ▪ Tried and failed 3 appropriate formulary options, if available. If less than 3, they have tried all formulary options ▪ Has contraindications to all formulary options ▪ Provider has given justifications for the absolute clinical need of the requested medication without trial or failure of alternatives o If the request is for a multi-source brand, the patient has tried & failed the generic alternative or has a contraindication to the generic o If the request is for a combination product, the provider has given justification that the individual drug products would not be appropriate • Minimum qualifications for reviewers: o 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):	• Randomized Controlled Trials (RCT), • randomized, blinded, placebo- controlled clinical systematic reviews, • observational, descriptive and panel studies that are non-experimental, and • professional recommendations based upon valid assessment of the available literature. For Prescription Drug Benefits - Experimental, Investigational, and Unproven only is applicable to medications that are either 1) Non-Formulary OR 2) require Prior Authorization. • The same Non-Formulary Exceptions policy is used for all medication classifications to provide appropriate E/I overrides of formulary status. 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If less than 3, they have tried all formulary options ▪ Has contraindications to all formulary options ▪ Provider has given justifications for the absolute clinical need of the requested medication without trial or failure of alternatives o If the request is for a multi-source brand, the patient has tried & failed the generic alternative or has a contraindication to the generic o If the request is for a combination product, the provider has given justification that the individual drug products would not be appropriate • Minimum qualifications for reviewers: o 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):

o 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 approve. 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. o If a member does not meet requirements laid out in Prior Authorization guidelines, they will be issued a denial. If the member elects to appeal, they will be asked to 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. o 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.	o 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 approve. 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. o If a member does not meet requirements laid out in Prior Authorization guidelines, they will be issued a denial. If the member elects to appeal, they will be asked to 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. o 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:	
Wellfleet 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. An "in operation" review of claims data and utilization review data from a sampling of Wellfleet administered 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 Wellfleet's application of the Experimental, Investigational, and Unproven NQTL, specifically approvals and denial information, revealed no statistically significant discrepancies in EIU denial rates as-between MH/SUD and M/S benefits. For Prescription Drug Benefits - An audit was completed of non-formulary medication exception requests where the submitting provider indicated 'No' under the question 'Is this product being requested for either an **FDA approved indication**'? In Calendar year 2024, there were 204 submissions indicating 'No' to this question. Of the 204, 20 were MH/SUD medications and 184 were M/S. Of the 20 MH/SUD medication requests, 18 were approved and 2 were denied (10%). Of the 184 M/S medication requests, 146 were approved and 38 were denied (20%). All denials were re-reviewed and denied appropriately for uses that were considered unsafe or ineffective. Also, an audit was completed of Prior Authorization requests that indicated a diagnosis separate from what was included in the guideline. In Calendar year 2024, there were 142 submissions	Wellfleet 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. An "in operation" review of claims data and utilization review data from a sampling of Wellfleet administered 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 Wellfleet's application of the Experimental, Investigational, and Unproven NQTL, specifically approvals and denial information, revealed no statistically significant discrepancies in EIU denial rates as-between MH/SUD and M/S benefits. For Prescription Drug Benefits - An audit was completed of non-formulary medication exception requests where the submitting provider indicated 'No' under the question 'Is this product being requested for either an **FDA approved indication**'? In Calendar year 2024, there were 204 submissions indicating 'No' to this question. Of the 204, 20 were MH/SUD medications and 184 were M/S. Of the 20 MH/SUD medication requests, 18 were approved and 2 were denied (10%). Of the 184 M/S medication requests, 146 were approved and 38 were denied (20%). All denials were re-reviewed and denied appropriately for uses that were considered unsafe or ineffective. Also, an audit was completed of Prior Authorization requests that indicated a diagnosis separate from what was included in the guideline. In Calendar year 2024, there were 142 submissions

indicating 'No' to this question. Of the 142, 7 were MH/SUD medications and 135 were M/S. Of the 7 MH/SUD medication requests, 4 were approved and 3 were denied (43%). Of the 135 M/S medication requests, 62 were approved and 73 were denied (54%). All denials were re-reviewed and denied appropriately for uses that were considered unsafe or ineffective.	indicating 'No' to this question. Of the 142, 7 were MH/SUD medications and 135 were M/S. Of the 7 MH/SUD medication requests, 4 were approved and 3 were denied (43%). Of the 135 M/S medication requests, 62 were approved and 73 were denied (54%). All denials were re-reviewed and denied appropriately for uses that were considered unsafe or ineffective.

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*

As written:

Wellfleet's methodology and processes for determining whether M/S 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. This is evidenced by the application of the same NQTL standard across M/S and MH/SUD benefits, as well as the reviews performed for M/S and MH/SUD services.

Moreover, 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, Wellfleet concludes that the NQTL was applied comparably and no more stringently to MH/SUD benefits than to M/S benefits, in operation.

For Prescription Drug Benefits, the methodology and processes for determining whether M/S medications are experimental, investigational and/or unproven are comparable and no more stringent than the methodology and processes for determining whether MH/SUD medications are experimental, investigational and/or unproven. Both classifications of medications have the same requirements – that the medication is approved for the requested use by the FDA, or that the medication has supporting data in a peer reviewed medical journal or clinical practice guidelines. The audit that was performed to ensure compliance showed that the policies were being utilized appropriately, issuing denials for medications with unproven uses.