NQTL: Medical Necessity Criteria Development

Classification(s): Pharmacy

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:[1]

"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.

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:[2]	***Step 1(b): Identify the MH/SUD benefits/services for which Medical Necessity Criteria Development is required***:[3]
All benefits and services requiring Prior Authorization, as seen in 'Covered Services' attachment	All benefits and services requiring Prior Authorization, as seen in 'Covered Services' attachment

[1] This section is responsive to Requirement 1 in *FAQ Part 45* at 4.
[2] This section is responsive to Requirement 2 in *FAQ Part 45* at 4.
[3] *Id.*

<table>
<tr><th colspan="2">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[4]</th></tr>
<tr><td>Medical/Surgical:

Wellfleet applies the following factors to determine whether to develop or adopt a medical necessity policy:
1. Lack of adherence to quality standards
2. High variability in cost within drugs in a given therapeutic class
3. 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

These factors are applied identically for both M/S & MH/SUD classifications.

Factors Considered but rejected:
No other factors were considered and rejected.
Weighting:
No factors are weighted more heavily than others.
There is no Artificial Intelligence application utilized for prescription medical necessity.</td><td>MH/SUD:

Wellfleet applies the following factors to determine whether to develop or adopt a medical necessity policy:
1. Lack of adherence to quality standards
2. High variability in cost within drugs in a given therapeutic class
3. Anticipated excessive utilization

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

These factors are applied identically for both M/S & MH/SUD classifications.

Factors Considered but rejected:
No other factors were considered and rejected.
Weighting:
No factors are weighted more heavily than others.
There is no Artificial Intelligence application utilized for prescription medical necessity.</td></tr>
<tr><th colspan="2">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.[5]</th></tr>
<tr><td>Medical/Surgical:
1. 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 peer-reviewed medical literature (located within the PubMed on the NIH database).
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</td><td>MH/SUD:
1. 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 treatment guidelines, nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature (located within the PubMed on the NIH database).</td></tr>
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[4] This section is responsive to Requirement 3 in *FAQ Part 45* at 4.
[5] This section is responsive to Requirements 3 and 4 in *FAQ Part 45* at 4.

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 guidelines, etc. • Source for Evidentiary Standard: Sections 1-14 of the FDA label (Indications & Usage, Dosage & Administration, Dosage Forms and Strengths, Contraindications, Warnings & Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations, Overdosage, Description, Clinical Pharmacology, Nonclinical Toxicology, and Clinical Studies), Minutes from Pharmacy and Therapeutics Committee Discussions, and professional treatment algorithm's from the medical literature 2. **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. • Source for Evidentiary Standard: Generic Therapeutic Classification (GTC), Specific Therapeutic Classification (STC) and Hierarchal Ingredient Code (HIC) are utilized through FDB and MediSpan to classify 'therapeutic class' for both MS and MH/SUD medications. Costs are determined based on Average Wholesale Price from FDB for comparison, based on a normal month supply 3. **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 nationally recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature (located within the PubMed on the NIH database). **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 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 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. • Source for Evidentiary Standard: Dosage & Administration section from FDA labeling	**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 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. Source for Evidentiary Standard: Sections 1-14 of the FDA label (Indications & Usage, Dosage & Administration, Dosage Forms and Strengths, Contraindications, Warnings & Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations, Overdosage, Description, Clinical Pharmacology, Nonclinical Toxicology, and Clinical Studies), Minutes from Pharmacy and Therapeutics Committee Discussions, and professional treatment algorithm's from the medical literature 2.**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. 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Costs are determined based on Average Wholesale Price from FDB for comparison, based on a normal month supply 3.**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-reviewed medical literature (located within the PubMed on the NIH database). **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. 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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]

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:	***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/formularies/. 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.	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/formularies/. 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, 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	*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, 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

[6] This section is responsive to Requirements 5-7 in *FAQ Part 45* at 4.

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, peer-reviewed medical literature, and national compendia. o Wellfleet's Clinical Pharmacist utilizes the sources listed above in the creation of this criteria. • After finalization of the drug-specific 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. *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.	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, peer-reviewed medical literature, and national compendia. • Wellfleet's Clinical Pharmacist utilizes the sources listed above in the creation of this criteria. • After finalization of the drug-specific 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. *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	***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 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 2024 were 96.2% for M/S reviews.	**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 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 2024 were 95.3% 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*[7]

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, *as written*, 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 95%. 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 analysis demonstrates its Medical Necessity Criteria Development practices are compliant with MHPAEA.

[7] This section is responsive to Requirement 8 in *FAQ Part 45* at 4.