NQTL: Prior Authorization

Classification(s): 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:[1]

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.

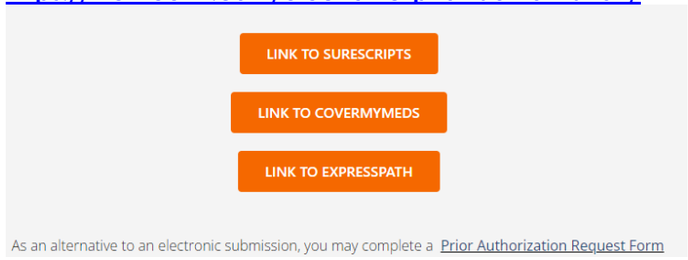
Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Prior Authorization NQTL and the guidelines that drive the decisions by ESI are approved by Wellfleet's internal Pharmacy and Therapeutics Committee (P&T) and Value Assessment Committee (VAC).

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."

Prescription Drug Prior Authorization information is described in several locations and does not discriminate or delineate between MS and MH/SUD medications. The same listing/set of guidelines is utilized for both the MS and MH/SUD classification, to provide a holistic view of all requirements under the plan. Our full listing of prescription drug products requiring prior authorization can be found in both our prescription drug formulary and prior authorization guidelines, found here: Formularies - Wellfleet Rx

When prior authorization is not received or is denied under the pharmacy benefit, the claim will continue to reject for 'Prior Authorization Required' at point of sale. A paid claim will not be transmitted to the filling pharmacy unless a prior authorization is received and approved.

TO INITIATE PRIOR AUTHORIZATION PROCESS FOR PHARMACY:
https://wellfleetrx.com/electronic-prior-authorization/



[1] 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:[2] Prior Authorization is required for some, but not all, M/S medications. Please see attached (Covered Services Attachment) which details benefits subject to PA	***Identify the MH/SUD benefits/services for which Prior Authorization is required***:[3] Prior Authorization is required for some, but not all, MH/SUD medications. 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[4]	
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) These factors are applied identically for both M/S & MH/SUD classifications. **Factors Considered but rejected**: No other factors were considered and rejected. **Weighting:** Weighting of factors is described below in Step 3. There is no Artificial Intelligence application utilized for prescription prior authorization.	**MH/SUD**: 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) These factors are applied identically for both M/S & MH/SUD classifications. **Factors Considered but rejected:** No other factors were considered and rejected. **Weighting:** Weighting of factors is described below in Step 3. There is no Artificial Intelligence application utilized for prescription prior authorization.
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.	

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

Medical/Surgical: Factors for determining whether to apply PA: 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 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 **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. • 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	**Medical/Surgical:** **Factors for determining whether to apply PA:** **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 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 **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. • 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 4. **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**: The Value Assessment Committee utilizes a claims 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. This claims data is sourced from our contracted PBM, Express Scripts, and encompasses all paid claims for the plan year that have not been returned to stock. The VAC determines the number of members that will be negatively impacted by prior authorization additions. Threshold for 'negative member impact' is 5% of total membership utilizing the product that a PA is being considered for. 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 put the interest of our members first and not assign a PA designation. • Source for Evidentiary Standard: Internal paid claims data from Express Scripts, excluding reversed claims	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 **4. 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:** The Value Assessment Committee utilizes a claims 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. This claims data is sourced from our contracted PBM, Express Scripts, and encompasses all paid claims for the plan year that have not been returned to stock. The VAC determines the number of members that will be negatively impacted by prior authorization additions. Threshold for 'negative member impact' is 5% of total membership utilizing the product that a PA is being considered for. 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 put the interest of our members first and not assign a PA designation. • Source for Evidentiary Standard: Internal paid claims data from Express Scripts, excluding reversed claims
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.	
All information below is applicable to both M/S and MH/SUD classifications Key steps in the process for developing prior authorization standards: • After determination is made by the P&T Committee and Value Assessment Committee to assign Prior Authorization to a particular drug product based on factors, sources, and evidentiary standards listed above, the prior authorization 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 and 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,	All information below is applicable to both M/S and MH/SUD classifications Key steps in the process for developing prior authorization standards: • After determination is made by the P&T Committee and Value Assessment Committee to assign Prior Authorization to a particular drug product based on factors, sources, and evidentiary standards listed above, the prior authorization 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 and 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 all 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, 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.

Policy Review Analysis:

- In review of the MH/SUD in comparison to M/S written prior authorization policies, 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, as listed above in Step 2. This analysis finds the two sets of criteria (MH/SUD and M/S)from the same sources to be similar in clinical requirements for medical necessity. All policies

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 all 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, 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.

Policy Review Analysis:

- In review of the MH/SUD in comparison to M/S written prior authorization policies, 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, as listed above in Step 2. This analysis finds the two sets of criteria (MH/SUD and M/S)from the same sources to be similar in clinical requirements for medical necessity. All policies

were reviewed and approved by the same P&T Committee. An overview of the analysis and the medications reviewed is below (see full PA requirements on the Wellfleet Rx site, listed in Step 1):

		Does the Criteria Include:			
Policy Name	**Class**	**FDA Approved Indication**	**Age restrictions**	**Alignment with package insert**	**Particular Specialty**
Lucemyra	MHSUD	Yes	Yes, mirroring FDA approval	Yes	No
Probuphine	MHSUD	Yes	No, mirroring FDA approval	Yes	Yes (REMS certified)
Sublocade	MHSUD	Yes	No, mirroring FDA approval	Yes	No
Sunosi	MHSUD	Yes	Yes, mirroring FDA approval	Yes	Yes (neurologist or sleep medicine specialist)
Addyi	MHSUD	Yes	Yes, mirroring FDA approval	Yes	No
Hetlioz	MHSUD	Yes	Yes, mirroring FDA approval	Yes	Yes (sleep medicine specialist)
Taltz	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (dermatologist, rheumatologist
Takhzyro	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (hematologist, allergist, immunologist)

were reviewed and approved by the same P&T Committee. An overview of the analysis and the medications reviewed is below (see full PA requirements on the Wellfleet Rx site, listed in Step 1):

		Does the Criteria Include:			
Policy Name	**Class**	**FDA Approved Indication**	**Age restrictions**	**Alignment with package insert**	**Particular Specialty**
Lucemyra	MHSUD	Yes	Yes, mirroring FDA approval	Yes	No
Probuphine	MHSUD	Yes	No, mirroring FDA approval	Yes	Yes (REMS certified)
Sublocade	MHSUD	Yes	No, mirroring FDA approval	Yes	No
Sunosi	MHSUD	Yes	Yes, mirroring FDA approval	Yes	Yes (neurologist or sleep medicine specialist)
Addyi	MHSUD	Yes	Yes, mirroring FDA approval	Yes	No
Hetlioz	MHSUD	Yes	Yes, mirroring FDA approval	Yes	Yes (sleep medicine specialist)
Taltz	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (dermatologist, rheumatologist
Takhzyro	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (hematologist, allergist, immunologist)

Zolgensma	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (neuromuscular specialist or SMA specialist)
Isturisa	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (endocrinologist)
Kevzara	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (rheumatologist)
Jynarque	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (nephrologist)

Ongoing Monitoring Activities:

- All policies are reviewed and updated based on clinical guidelines, FDA labeling, safety, etc. updates at least annually (see sources, above). 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.

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

- An audit was conducted of both MS and MH/SUD prior authorization approvals to check the length of approval. Authorizations for both M/S and MH/SUD 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. An audit was conducted of both MS and MH/SUD prior authorization approvals to check length of approval. In all instances, both MS and MHSUD, approved prior authorizations lasted for exactly 365 days from the day of approval. 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

Zolgensma	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (neuromuscular specialist or SMA specialist)
Isturisa	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (endocrinologist)
Kevzara	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (rheumatologist)
Jynarque	MS	Yes	Yes, mirroring FDA approval	Yes	Yes (nephrologist)

Ongoing Monitoring Activities:

- All policies are reviewed and updated based on clinical guidelines, FDA labeling, safety, etc. updates at least annually (see sources, above). 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.

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

- An audit was conducted of both MS and MH/SUD prior authorization approvals to check the length of approval. Authorizations for both M/S and MH/SUD 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. An audit was conducted of both MS and MH/SUD prior authorization approvals to check length of approval. In all instances, both MS and MHSUD, approved prior authorizations lasted for exactly 365 days from the day of approval. 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 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 on 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 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.

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 guideline change includes any criteria that differs from the FDA approved labeling information, it will also require

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 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 on 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 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.

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 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. All 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. All guidelines are reviewed and approved by the same committee. o 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. External Subject Matter Experts are allowed per the P&T Policy to attend meetings for discussion purposes, however none joined during the 2024 Calendar Year. P&T utilizes professional expertise, along with the sources listed above (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), for discussions. o P&T is currently composed of licensed and practicing physicians and pharmacists. Specialties that are represented include: Family Medicine, Internal Medicine, Psychiatry, Child Psychiatry, Neurology, Oncology, Dermatology, Pediatrics, Gastroenterology, Specialty Pharmacy, and Obstetrics. There are currently 12 voting members of the committee, who meet quarterly. Quarterly time allotted for meeting materials is four hours. • Value Assessment Committee (VAC) o 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. This committee is comprised of 8 members, representing the Healthcare Optimization/Clinical teams, finance teams, executive leadership, client relations team, CMO, Medical Economics, and Member Experience teams. The VAC is not split between MS and MHSUD classifications; the same team reviews all medications. At least quarterly, the team will receive notes from P&T meetings for review. Meetings will be conducted ~1 week after materials are distributed to the committee and will be 1-2 hours in length to discuss new medications and alterations to prior authorization strategy of existing medications. Minutes will be distributed for review after the meetings and a vote shall be conducted to ensure all members agree with the proposed changes to utilization/formulary strategy. 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 to set Prior Authorization.	justification and approval from the P&T Committee. All 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. All guidelines are reviewed and approved by the same committee. o 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. External Subject Matter Experts are allowed per the P&T Policy to attend meetings for discussion purposes, however none joined during the 2024 Calendar Year. P&T utilizes professional expertise, along with the sources listed above (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), for discussions. o P&T is currently composed of licensed and practicing physicians and pharmacists. Specialties that are represented include: Family Medicine, Internal Medicine, Psychiatry, Child Psychiatry, Neurology, Oncology, Dermatology, Pediatrics, Gastroenterology, Specialty Pharmacy, and Obstetrics. There are currently 12 voting members of the committee, who meet quarterly. Quarterly time allotted for meeting materials is four hours. • Value Assessment Committee (VAC) o 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. This committee is comprised of 8 members, representing the Healthcare Optimization/Clinical teams, finance teams, executive leadership, client relations team, CMO, Medical Economics, and Member Experience teams. The VAC is not split between MS and MHSUD classifications; the same team reviews all medications. At least quarterly, the team will receive notes from P&T meetings for review. Meetings will be conducted ~1 week after materials are distributed to the committee and will be 1-2 hours in length to discuss new medications and alterations to prior authorization strategy of existing medications. Minutes will be distributed for review after the meetings and a vote shall be conducted to ensure all members agree with the proposed changes to utilization/formulary strategy. 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 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 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. • 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. • 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.	• 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 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. 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.	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.

M/S PA Requirements	
Total M/S Drugs	8,400
Total M/S Drugs Requiring PA	1,552
PA Required Rate	18.5%

- 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 M/S drugs was less than 1 day

- We also completed an analysis of denial rates for requests for Prior Authorization in calendar year 2024. Results can be seen in the table below. Most recent Interrater reliability results for reviews performed were 96.2% for M/S reviews.

Global M/S PA Analysis	
Total PA Requests	4425
Total PA Approvals	3094
Total PA Denials	1331
PA Approval Rate	69.9%
PA Denial Rate	30.1%

- There were 94 appeals for M/S PA requests that were originally denied. Of these 94, 46 were denied upon appeal (49%) and 48 were approved upon appeal (51%). For MH/SUD, there were 20 appeals. Of these 20, 8 were denied upon appeal (40%) and 12 were approved upon appeal (60%). The approval/denial rate difference is not statistically significant.

- We also completed an analysis at the Wellfleet National book of business level of the turnaround times for PA requests to be issued either an approval or denial. On average, the turnaround times from submission to determination of approval/denial for M/S & MH/SUD drugs were less than 1 day. The difference (0.03 days), is not statistically significant. Results are below:

MH/SUD PA Requirements	
Total MH/SUD Drugs	783
Total MH/SUD Drugs Requiring PA	44
PA Required Rate	5.6%

- 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 2024. Results can be seen in the table below. Most recent Interrater reliability results for reviews performed were 95.3% for MH/SUD reviews.

Global MH/SUD PA Analysis	
Total PA Requests	831
Total PA Approvals	621
Total PA Denials	210
PA Approval Rate	74.7%
PA Denial Rate	25.3%

- There were 94 appeals for M/S PA requests that were originally denied. Of these 94, 46 were denied upon appeal (49%) and 48 were approved upon appeal (51%). For MH/SUD, there were 20 appeals. Of these 20, 8 were denied upon appeal (40%) and 12 were approved upon appeal (60%). The approval/denial rate difference is not statistically significant.

- We also completed an analysis at the Wellfleet National book of business level of the turnaround times for PA requests to be issued either an approval or denial. On average, the turnaround times from submission to determination of approval/denial for M/S & MH/SUD drugs were less than 1 day. The difference (0.03 days), is not statistically significant. Results are below:

Class	Total Cases	Approved Cases	Approved Turnaround Time	Denied Cases	Denied Turnaround Time	Total Average Turnaround
MS	4425	3094	0.09 days	1331	0.3 days	0.15 days
MHSUD	831	621	0.12 days	210	0.1days	0.12 days

Specifically, with respect to Rx prior authorization, Wellfleet performs a review of data, at least annually, using the following steps (results above in step 4):

1. Select random sampling of prior authorization guidelines for MH/SUD and for M/S medications.
2. Compare factors and evidentiary standards used for the development of each guideline.
3. Confirm restrictions based on provider specialty are not applied more stringently for MH/SUD drugs as compared to M/S drugs.
4. Review Prior Authorization guidelines to confirm that they do not include language that would result in MH/SUD drug reviews to be more stringent than M/S review.

Factors and evidentiary standards are utilized identically between the classifications. A greater percentage of MS PA's required a particular specialist to be the prescribing healthcare provider compared to MHSUD (100% vs 50%, respectively).

Also, upon internal determination and P&T approval of Prior Authorization requirements, decision-tree mapping is submitted to Express Scripts for coding and implementation in their system. Turnaround time from submission to 'go-live' is set to 14 days for both MS and MHSUD medications. This is monitored upon submission and verified by Express Scripts clinical team upon coding completion. There were no instances of delayed coding in 2023. Time from internal approval for prior authorization requirements and them going live for our members is consistent for both MS and MHSUD medications, showing operational implementation parity.

Class	Total Cases	Approved Cases	Approved Turnaround Time	Denied Cases	Denied Turnaround Time	Total Average Turnaround
MS	4425	3094	0.09 days	1331	0.3 days	0.15 days
MHSUD	831	621	0.12 days	210	0.1days	0.12 days

Specifically, with respect to Rx prior authorization, Wellfleet performs a review of data, at least annually, using the following steps (results above in step 4):

1. Select random sampling of prior authorization guidelines for MH/SUD and for M/S medications.
2. Compare factors and evidentiary standards used for the development of each guideline.
3. Confirm restrictions based on provider specialty are not applied more stringently for MH/SUD drugs as compared to M/S drugs.
4. Review Prior Authorization guidelines to confirm that they do not include language that would result in MH/SUD drug reviews to be more stringent than M/S review.

Factors and evidentiary standards are utilized identically between the classifications. A greater percentage of MS PA's required a particular specialist to be the prescribing healthcare provider compared to MHSUD (100% vs 50%, respectively).

Also, upon internal determination and P&T approval of Prior Authorization requirements, decision-tree mapping is submitted to Express Scripts for coding and implementation in their system. Turnaround time from submission to 'go-live' is set to 14 days for both MS and MHSUD medications. This is monitored upon submission and verified by Express Scripts clinical team upon coding completion. There were no instances of delayed coding in 2023. Time from internal approval for prior authorization requirements and them going live for our members is consistent for both MS and MHSUD medications, showing operational implementation parity.

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, Head of Pharmacy 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. Wellfleet's audit of MHSUD vs MS drugs showed that all sampled PAs required FDA indication, had an age restriction if applicable per the FDA, and aligned with requirements included in the FDA approved drug packaging label. A greater percentage of MS PA's required a particular specialist to be the prescribing healthcare provider compared to MHSUD (100% vs 50%, respectively). 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 MH/SUD drugs are valid for 365 days from approval. 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, as written, 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 (5.6%) is much lower than the percentage of M/S drugs requiring prior authorization (18.5%). The denial rate for MH/SUD drug requests (25.3%) is also lower than the denial rate for M/S drug requests (30.1%). The virtual material 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.

Thus, we conclude 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.

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.