NQTL: Step Therapy

Classification(s): Prescription Drugs

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

Provide a clear description of the specific NQTL, plan terms, and policies at issue:[1]

From Wellfleet's standard Certificate of Coverage Template: Step therapy (ST) is a process in which the Member may need to use one (1) or more types of Prescription Drug before We will Cover another as Medically Necessary. A "step therapy protocol" means Our policy, protocol or program that establishes the sequence in which We approve Prescription Drugs for a Member's medical condition.

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

Step Therapy is defined, in the Wellfleet Pharmacy and Therapeutics Committee Policy, as "Step Therapy: A process in which the member may need to use one (1) or more types of Prescription Drug before coverage of a second Prescription Drug."

Identify the M/S drugs for which Step Therapy is required:[2]	***Identify the MH/SUD drugs for which Step Therapy is required***:[3]
Step therapy applies to some, but not all, M/S Drugs. Please see attached (Covered Services Attachment) which details benefits subject to ST	Step therapy applies to some, but not all, MH/SUD drugs. Please see attached (Covered Services Attachment) which details benefits subject to ST

Step 2 – Identify the factors used to determine that Step Therapy will apply to mental health or substance use disorder benefits and medical or surgical drugs[4]

Medical/Surgical:	**MH/SUD**:
Factors for determining whether a prescription drug product will have Step therapy or not: 1. High variability in cost within drugs in a given therapeutic class 2. Availability of Cost-Effective alternatives 3. Member Impact (this factor is used only to determine when ST should not be applied)	Factors for determining whether a prescription drug product will have Prior Authorization or not: 1. High variability in cost within drugs in a given therapeutic class 2. Availability of Cost-Effective alternatives 3. Member Impact (this factor is used only to determine when ST should not be applied)

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

Factors Considered but rejected (same for M/S and MH/SUD): No other factors were considered and rejected. **Weight (same for M/S and MH/SUD):** Weighting of factors is described below in Step 3. There is no Artificial Intelligence application utilized for prescription step therapy.	**Factors Considered but rejected (same for M/S and MH/SUD):** No other factors were considered and rejected. **Weight (same for M/S and MH/SUD):** Weighting of factors is described below in Step 3. There is no Artificial Intelligence application utilized for prescription step therapy.
Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Step Therapy to mental health or substance use disorder benefits and medical or surgical benefits.	
Medical/Surgical: Factor 1: High variability in cost within drugs in a given therapeutic class o **Source:** First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis. o **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, and internal claims data. High-cost variability is defined as a 20% monthly cost difference for all medication categories. Factor 2: Availability of Cost-Effective alternatives o **Source:** First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines, peer-reviewed medical literature o **Evidentiary Standard:** Availability of alternate therapies (brand/generic). This is determined through discussions at P&T Committee meetings, that are based on therapeutic class reviews and new drug reviews. These are created using the sources above by Wellfleet's Clinical Pharmacist. These reviews contain information on indications, dosing & administration, clinical and comparative efficacy, clinical guidelines, contraindications & special populations, etc. The P&T Committee reviews clinical guidelines and nationally accepted standards of care to assess whether recommended alternative therapies exist. The P&T Committee discussions may determine that two or more drugs are expected to achieve clinically equivalent therapeutic outcomes. Having two or more drugs that are expected to achieve a clinically equivalent therapeutic outcome constitutes a potential 'cost-effective alternative', if the net cost per day supply is greater than 20% different. These discussions, along with the other factors listed in	**MH/SUD**: Factor 1: High variability in cost within drugs in a given therapeutic class o **Source:** First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis. o **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, and internal claims data. High-cost variability is defined as a 20% monthly cost difference for all medication categories. Factor 2: Availability of Cost-Effective alternatives o **Source:** First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines, peer-reviewed medical literature o **Evidentiary Standard:** Availability of alternate therapies (brand/generic). This is determined through discussions at P&T Committee meetings, that are based on therapeutic class reviews and new drug reviews. These are created using the sources above by Wellfleet's Clinical Pharmacist. These reviews contain information on indications, dosing & administration, clinical and comparative efficacy, clinical guidelines, contraindications & special populations, etc. The P&T Committee reviews clinical guidelines and nationally accepted standards of care to assess whether recommended alternative therapies exist. The P&T Committee discussions may determine that two or more drugs are expected to achieve clinically equivalent therapeutic outcomes. Having two or more drugs that are expected to achieve a clinically equivalent therapeutic outcome constitutes a potential 'cost-effective alternative', if the net cost per day supply is greater than 20% different. These discussions, along with the other factors listed in

this section, guide the recommendations that are brought to the Value Assessment Committee for final determination on formulary status and tiering. ▪ Source for Evidentiary Standard: P&T minutes, therapeutic class reviews, nationally accepted standards of care(through the AMA, APA, ASAM, ACC, etc., or within the PubMed from NIH) Factor 3: Member Impact (this factor is used only to determine when ST should not be applied) o **Source:** Internal claims data, internal market and competitive analysis o **Evidentiary Standard:** The number of members that will be negatively impacted by adding a step therapy. This is only taken into account to decide not to apply a step therapy requirement. If both factors 1 & 2 suggest removing a drug product from formulary or shifting from 'preferred' tier to 'non-preferred', but there would be a large member impact, we would put the interest of our members first and not make changes. The threshold for 'negative member impact' is 5% of total membership utilizing the product that an addition would affect. ▪ Source for Evidentiary Standard: Internal paid claims data from Express Scripts, excluding reversed claims The Value Assessment Committee considers factors 1 & 2 equally in order to make a determination as to whether Step Therapy should be applied. If both factors 1 & 2 are met, the VAC considers Factor 3 (member impact) to assess whether Step therapy should be applied in light of anticipated member impact.	this section, guide the recommendations that are brought to the Value Assessment Committee for final determination on formulary status and tiering. ▪ Source for Evidentiary Standard: P&T minutes, therapeutic class reviews, nationally accepted standards of care(through the AMA, APA, ASAM, ACC, etc., or within the PubMed from NIH) Factor 3: Member Impact (this factor is used only to determine when ST should not be applied) o **Source:** Internal claims data, internal market and competitive analysis o **Evidentiary Standard:** The number of members that will be negatively impacted by adding a step therapy. This is only taken into account to decide not to apply a step therapy requirement. If both factors 1 & 2 suggest removing a drug product from formulary or shifting from 'preferred' tier to 'non-preferred', but there would be a large member impact, we would put the interest of our members first and not make changes. The threshold for 'negative member impact' is 5% of total membership utilizing the product that an addition would affect. ▪ Source for Evidentiary Standard: Internal paid claims data from Express Scripts, excluding reversed claims The Value Assessment Committee considers factors 1 & 2 equally in order to make a determination as to whether Step Therapy should be applied. If both factors 1 & 2 are met, the VAC considers Factor 3 (member impact) to assess whether Step therapy should be applied in light of anticipated member impact.
Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.	
Briefly describe the processes by which Step Therapy is applied to M/S benefits: *Timelines and deadlines, frequency of review*: • Turnaround times for review and either approving or denying a ST request are based on state requirements. However, on average across Wellfleet's book of business ST requests are processed within 1 business day. • Authorizations across the board for both M/S and MHSUD drugs are valid for 365 days from approval. The only exceptions here are for products that have regulatory implications, which will be approved based on the regulatory statute. • Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance. *Forms and/or other information required to be submitted by the provider*: • Providers can request Step Therapy Exceptions by calling Express Scripts Prior Authorization department directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a standard Prior Authorization Request Form and faxing	***Briefly describe the processes by which Step Therapy is applied to MH/SUD benefits***: *Timelines and deadlines, frequency of review*: • Turnaround times for review and either approving or denying a ST request are based on state requirements. However, on average across Wellfleet's book of business ST requests are processed within 1 business day. • Authorizations across the board for both M/S and MHSUD drugs are valid for 365 days from approval. The only exceptions here are for products that have regulatory implications, which will be approved based on the regulatory statute. • Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance. *Forms and/or other information required to be submitted by the provider*: • Providers can request Step Therapy Exceptions by calling Express Scripts Prior Authorization department directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a standard Prior Authorization Request Form and faxing

directly to Express Scripts Prior Authorization department. Submission of medical chart notes / patient drug history may be required for these Step Therapy Exceptions.

- If a member has a history of the required step drugs in their profile with Express Scripts, they will automatically get a paid claim at point-of-sale without the provider being required to submit an exception request. This can be done for all drugs that require Step Therapy, regardless of drug classification.

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

- The P&T Policy & Procedures and Formulary Management Policy are reviewed at least annually to ensure there is no verbiage indicating a bias towards any particular subset of drugs. These policies dictate that all decisions should be based off the clinical merits of the drug, not the classification of drug itself.
- The most recent review of this policy was conducted over the course of 8 working hours. Particular attention was put on the classifications of "Mental Health/Substance Use Disorder" in order to most appropriately identify the medications that should be in this bucket. Additional Hierarchal Ingredient Codes (HICL) were added as cross-over medications (medications that can be utilized for both mental health and med/surg diagnoses. The additional HICL's were: 01608, 01621, 01629, 01641, 01642, 01643, 01656, 01745, 01884, 01893, 07378, and 26521. Other edits included updating titles for staff impacted by the policy and inclusion of definitions for GTC, STC, and HICL. The only other instances of calling out mental health medications is to reference MHPAEA and to describe that an annual analysis must be conducted. Snips of updates are included below.

  - ~~b.~~i. Mental Health/Substance Use Disorder medications shall be classified as any product with either a First DataBank Generic Therapeutic Class (GTC) Identifier of 80 or 83, or Specific Therapeutic Class (STC) Identifier of 00274, 00292, 00253,17889,07261, 00164, 03624, or 17391. Drugs that can be utilized for both Mental Health/Substance Use Disorder and Medical/Surgical conditions shall be considered 'cross-over' and shall be bucketed into both 'MH/SUD' and 'M/S' for any MHPAEA analysis performed. These medications shall be identified by Hierarchal Ingredient Code (HICL). Cross-over medications have a HICL of 01608, 01621, 01629, 01641, 01642, 01643, 01656, 01745, 01884, 01893, 07378, or 26521.

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- **Generic Therapeutic Class (GTC):** Broad class identification for medications. Provided by First DataBank.
- **Hierarchal Ingredient Code (HICL):** Generic ingredient identification for medications. Provided by First DataBank.

- **Specific Therapeutic Class (STC):** Narrow class identification for medications. Provided by First DataBank.

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. 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. Current specialties represented are: family medicine, internal medicine, hematology/oncology pharmacy, psychiatric pharmacy, OB/GYN, psychiatry, oncology, and pulmonology.
- Value Assessment Committee (VAC)
  - The VAC is responsible for determining tiering and Utilization Management decisions for drugs that are designed as 'include' by the P&T Committee. These drugs shall not be removed from formulary without prior approval from the P&T Committee. Also, determining coverage, tiering, and Utilization Management decisions for drugs that are designated as 'optional' by the P&T Committee.

Minimum qualifications for reviewers:

- To become members of the P&T Committee, the physicians must be board certified licensed physicians with over 5 years of experience in their respective fields. We use the clinical expertise of the P&T Committee members along with published clinical guidelines and scientific evidence to achieve consensus in order to set Quantity Limits.
- 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

- **Generic Therapeutic Class (GTC):** Broad class identification for medications. Provided by First DataBank.
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- Every PAR, UMP, Nurse, and Medical Director goes through extensive training to make sure we are providing the most complete and comprehensive service for each one of our members. The training consists of both in classroom, on the job shadowing, monthly

quality reviewing of cases, and weekly meetings to provide any new/updated information that needs to be shared with the teams. *Minimum standards to issue a denial*: • The same Exceptions policy, which is reviewed annually by the Pharmacy & Therapeutics Committee, is used for both MH/SUD and M/S drugs. It is also reviewed in order to determine whether there is any verbiage that would cause decisions regarding exceptions to the application of step therapy to be made out of parity. 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 medications that require step therapy. The exceptions policy currently requires one of four main points for approval, none of which are biased toward M/S or MH/SUD drugs: 1. The patient has a contraindication to the required Step drug; 2. The prescriber suspects the required Step drug to be ineffective for the patient; 3. The patient has tried a therapeutically equivalent dose of the required Step drug under the current or previous health plan for a long enough period of time to reach a therapeutic improvement and was discontinued due to lack of improvement; 4. The patient is currently receiving a positive outcome on the requested drug and should not discontinue. • If a member has not met criteria for Step therapy exception and provider cannot provide documentation as described above for an exception, they will be issued a denial • Depending on state requirements, a denial may only be issued by certain individuals with particular qualifications (e.g. physician with same/similar specialty licensed in same state, pharmacist, etc.). This is kept consistent for M/S and MH/SUD. *Factors influencing Step Therapy Determination analysis:* • An audit was conducted for a random subset of formulary medications that have a step therapy requirement, to ensure that the factors utilized to make this determination were used consistently. The findings from this audit are below. All products sampled had several cost-effective alternatives with AWP / unit at a statistically lower value. Alternatives were all sourced based on clinical practice guidelines pertinent to the medication analyzed and FDA prescribing information, and AWP was based on values found in First Databank.	quality reviewing of cases, and weekly meetings to provide any new/updated information that needs to be shared with the teams. *Minimum standards to issue a denial*: • The same Exceptions policy, which is reviewed annually by the Pharmacy & Therapeutics Committee, is used for both MH/SUD and M/S drugs. It is also reviewed in order to determine whether there is any verbiage that would cause decisions regarding exceptions to the application of step therapy to be made out of parity. 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 medications that require step therapy. The exceptions policy currently requires one of four main points for approval, none of which are biased toward M/S or MH/SUD drugs: 1. The patient has a contraindication to the required Step drug; 2. The prescriber suspects the required Step drug to be ineffective for the patient; 3. The patient has tried a therapeutically equivalent dose of the required Step drug under the current or previous health plan for a long enough period of time to reach a therapeutic improvement and was discontinued due to lack of improvement; 4. The patient is currently receiving a positive outcome on the requested drug and should not discontinue. • If a member has not met criteria for Step therapy exception and provider cannot provide documentation as described above for an exception, they will be issued a denial • Depending on state requirements, a denial may only be issued by certain individuals with particular qualifications (e.g. physician with same/similar specialty licensed in same state, pharmacist, etc.). This is kept consistent for M/S and MH/SUD. *Factors influencing Step Therapy Determination analysis:* • An audit was conducted for a random subset of formulary medications that have a step therapy requirement, to ensure that the factors utilized to make this determination were used consistently. The findings from this audit are below. All products sampled had several cost-effective alternatives with AWP / unit at a statistically lower value. Alternatives were all sourced based on clinical practice guidelines pertinent to the medication analyzed and FDA prescribing information, and AWP was based on values found in First Databank.

			Factors Utilized for Step Therapy Determination		
Medication Name	**Classification**	**Step Therapy**	**Availability of Cost-Effective alternatives**	**High variability in cost within drugs in a given therapeutic class**	**Member Impact**
Almotriptan Tablet	M/S	X	X - Rizatriptan Sumatriptan	X - Almotriptan AWP / unit - $42 Rizatriptan AWP / unit - $33 Sumatriptan AWP / unit - $25	
Carisoprodol Tablet	M/S	X	X - Baclofen Cyclobenzaprine Methocarbamol	X - Carisoprodol AWP / unit - $3.30 Baclofen AWP / unit - $2 Cyclobenzaprine AWP / unit - $1 Methocarbamol AWP / unit - $0.25	
Neupro Patch	M/S	X	X - Pramipexole Ropinirole	X - Neupro AWP / unit - $34 Pramipexole AWP / unit - $3 Ropinirole AWP / unit - $0.75	
Pancreaze Capsule	M/S	X	X - Creon Zenpep	X - Pancreaze AWP / unit - $7.50 Creon AWP / unit - $5 Zenpep AWP / unit - $5	
Risedronate Tablet	M/S	X	X - Alendronate Ibandronate	X - Risedronate AWP / unit - $320 Alendronate AWP / unit - $58 Ibandronate AWP / unit - $165	
Travatan Z Eye Drop	M/S	X	X - Bimatoprost Latanoprost	X - Travatan Z AWP / unit - $120 Bimatoprost AWP / unit - $30 Latanoprost AWP / unit - $8	

			Factors Utilized for Step Therapy Determination		
Medication Name	**Classification**	**Step Therapy**	**Availability of Cost-Effective alternatives**	**High variability in cost within drugs in a given therapeutic class**	**Member Impact**
Almotriptan Tablet	M/S	X	X - Rizatriptan Sumatriptan	X - Almotriptan AWP / unit - $42 Rizatriptan AWP / unit - $33 Sumatriptan AWP / unit - $25	
Carisoprodol Tablet	M/S	X	X - Baclofen Cyclobenzaprine Methocarbamol	X - Carisoprodol AWP / unit - $3.30 Baclofen AWP / unit - $2 Cyclobenzaprine AWP / unit - $1 Methocarbamol AWP / unit - $0.25	
Neupro Patch	M/S	X	X - Pramipexole Ropinirole	X - Neupro AWP / unit - $34 Pramipexole AWP / unit - $3 Ropinirole AWP / unit - $0.75	
Pancreaze Capsule	M/S	X	X - Creon Zenpep	X - Pancreaze AWP / unit - $7.50 Creon AWP / unit - $5 Zenpep AWP / unit - $5	
Risedronate Tablet	M/S	X	X - Alendronate Ibandronate	X - Risedronate AWP / unit - $320 Alendronate AWP / unit - $58 Ibandronate AWP / unit - $165	
Travatan Z Eye Drop	M/S	X	X - Bimatoprost Latanoprost	X - Travatan Z AWP / unit - $120 Bimatoprost AWP / unit - $30 Latanoprost AWP / unit - $8	

Adzenys Tablet	MH/SUD	X	X - Amphetamine Salts Methylphenidate	X - Adzenys AWP / unit - $21 Amphetamine Salts AWP / unit - $2 Methylphenidate AWP / unit - $1	
Belsomra Tablet	MH/SUD	X	X - Zolpidem Eszopiclone	X - Belsomra AWP / unit - $18 Zolpidem AWP / unit - $5 Eszopiclone AWP / unit - $12	
Emsam Patch	MH/SUD	X	X - Rasagaline Selegiline	X - Emsam AWP / unit - $86 Rasagaline AWP / unit - $22 Selegiline AWP / unit - $2	
Latuda Tablet	MH/SUD	X	X - Aripiprazole Risperidone Quetiapine	X - Latuda AWP / unit - $57 Aripiprazole AWP / unit - $5 Risperidone AWP / unit - $5 Quetiapine AWP / unit - $4	
Ramelteon Tablet	MH/SUD	X	X - Eszopiclone Temazepam Zolpidem	X - Eszopiclone AWP / unit - $12 Temazepam AWP / unit - $1 Zolpidem AWP / unit - $5	
Viibryd Tablet	MH/SUD	X	X - Citalopram Fluoxetine Sertraline	X - Viibryd AWP / unit - $14 Citalopram AWP / unit - $2 Fluoxetine AWP / unit - $2.50 Sertraline AWP / unit - $0.50	

Adzenys Tablet	MH/SUD	X	X - Amphetamine Salts Methylphenidate	X - Adzenys AWP / unit - $21 Amphetamine Salts AWP / unit - $2 Methylphenidate AWP / unit - $1	
Belsomra Tablet	MH/SUD	X	X - Zolpidem Eszopiclone	X - Belsomra AWP / unit - $18 Zolpidem AWP / unit - $5 Eszopiclone AWP / unit - $12	
Emsam Patch	MH/SUD	X	X - Rasagaline Selegiline	X - Emsam AWP / unit - $86 Rasagaline AWP / unit - $22 Selegiline AWP / unit - $2	
Latuda Tablet	MH/SUD	X	X - Aripiprazole Risperidone Quetiapine	X - Latuda AWP / unit - $57 Aripiprazole AWP / unit - $5 Risperidone AWP / unit - $5 Quetiapine AWP / unit - $4	
Ramelteon Tablet	MH/SUD	X	X - Eszopiclone Temazepam Zolpidem	X - Eszopiclone AWP / unit - $12 Temazepam AWP / unit - $1 Zolpidem AWP / unit - $5	
Viibryd Tablet	MH/SUD	X	X - Citalopram Fluoxetine Sertraline	X - Viibryd AWP / unit - $14 Citalopram AWP / unit - $2 Fluoxetine AWP / unit - $2.50 Sertraline AWP / unit - $0.50	

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

- To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply step therapy to M/S drugs, step therapy for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to step therapy. In total, M/S medications make up 91.5% of the total medications on the market, and MH/SUD medications make up 8.5% of the total medications on the market. See table below for M/S results.

M/S ST Requirements	
Total M/S Drugs	8,400
Total M/S Drugs Requiring ST	371
ST Required Rate	5%

We also completed an analysis of the turnaround times for ST requests to be issued either an approval or denial. On average, the turnaround time for M/S drugs was less than 1 day. Results are included in the table below. The value differences (0.2 days) is not statistically significant (CI -0.5% ; 0.7%).

- We also completed an analysis of denial rates for requests for Step Therapy in calendar year 2024. Results can be seen in the table below.

Global M/S ST Analysis	
Total ST Requests	1323
Total ST Approvals	1162
Total ST Denials	161
ST Approval Rate	87.8%
ST Denial Rate	12.2%
Average Turnaround Time	0.3 Calendar Days

- We also completed an audit of any Step Therapy changes that took place during 2023 to ensure that the addition or removal of step requirements was supported by the factors, sources, and evidentiary standards written in policy. The summary of changes

- To ensure that the processes, strategies, evidentiary standards, and other factors used to apply prior authorization to MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply step therapy to M/S drugs, step therapy for prescription drugs is analyzed semi-annually. One analysis we completed was a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to step therapy. In total, M/S medications make up 91.5% of the total medications on the market, and MH/SUD medications make up 8.5% of the total medications on the market. See table below for M/S results.

MH/SUD ST Requirements	
Total MH/SUD Drugs	783
Total MH/SUD Drugs Requiring ST	79
ST Required Rate	10%

We also completed an analysis of the turnaround times for ST requests to be issued either an approval or denial. On average, the turnaround time for MH/SUD drugs was less than 1 day. Results are included in the table below. The value differences (0.2 days) is not statistically significant (CI -0.5% ; 0.7%).

- We also completed an analysis of denial rates for requests for Step Therapy in calendar year 2024. Results can be seen in the table below.

Global MH/SUD ST Analysis	
Total ST Requests	282
Total ST Approvals	266
Total ST Denials	16
ST Approval Rate	94%
ST Denial Rate	6%
Average Turnaround Time	0.2 Calendar Days

- We also completed an audit of any Step Therapy changes that took place during 2023 to ensure that the addition or removal of step requirements was supported by the factors, sources, and evidentiary standards written in policy. The summary of changes that took place in 2023 are listed below, directly form the Value Assessment Committee

that took place in 2023 are listed below, directly form the Value Assessment Committee minutes. As can be seen, there was only one addition to the QL listing in 2023 for MH/SUD medications. All recommended QL additions were due to Safety or Anticipated Excessive Utilization.

Drug	Current Status	Recommendation	Classification	Reason	Negative Member Impact	Factors taken into consideration
PANCREAZE	NO ST	ADD ST THROUGH LOW COST ALTERNATIVES	MS	HIGH COST WITH ALT'S AVAILABLE	0	AVAILABILITY OF COST EFFECTIVE ALTERNATIVES, HIGH VARIABILITY IN COST
PERTZYE	NO ST	ADD ST THROUGH LOW COST ALTERNATIVES	MS	HIGH COST WITH ALT'S AVAILABLE	0	AVAILABILITY OF COST EFFECTIVE ALTERNATIVES, HIGH VARIABILITY IN COST
VTAMA	NO ST	ADD ST THROUGH LOW COST ALTERNATIVES	MS	HIGH COST WITH ALT'S AVAILABLE	0	AVAILABILITY OF COST EFFECTIVE ALTERNATIVES, HIGH VARIABILITY IN COST

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VTAMA	NO ST	ADD ST THROUGH LOW COST ALTERNATIVES	MS	HIGH COST WITH ALT'S AVAILABLE	0	AVAILABILITY OF COST EFFECTIVE ALTERNATIVES, HIGH VARIABILITY IN COST

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

As Written: The process for creating a step therapy policy for a drug is the same for both M/S and MH/SUD drugs. Providers can request Step Therapy Exceptions by calling Express Scripts Prior Authorization department directly, utilizing CoverMyMeds, Express Path, or SureScripts ePA software, or by completing a standard Prior Authorization Request Form and faxing directly to Express Scripts Prior Authorization department. Submission of medical chart notes / patient drug history may be required for these Step Therapy Exceptions. Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Step Therapy NQTL and the guidelines that drive the decisions by ESI are approved by Wellfleet's internal Pharmacy and Therapeutics Committee (P&T) and Value Assessment Committee (VAC). They are reviewed by the P&T Committee, and ultimately subject to approval by the VAC Committee on an annual basis.

Whether to recommend a step therapy policy for a drug is based on three factors: 1) high variability in cost within drugs in a given therapeutic class, 2) availability of cost-effective alternatives, and 3) member impact. These factors are based on First Databank (FDB), internal market and competitive analysis, therapeutic class total net cost analysis, FDA prescribing information, professionally recognized treatment guidelines, peer-reviewed medical literature, internal claims data, internal market and competitive analysis. These factors, standards and sources are the same regardless of whether a drug is a M/S or MH/SUD drug. An audit was performed to ensure parity, which showed that 100% of sampled M/S and 100% of MH/SUD medications that were

indicated to have a step therapy on the formulary were impacted by the factors and sources equally. An audit & approval of the Step Therapy Exception Criteria, by both internal Wellfleet employees and the external Pharmacy and Therapeutics Committee, showed no discriminatory language or additional requirements surrounding MH/SUD medications.

In Operation: In operation, for both M/S and MH/SUD drugs, authorization approval rates are highly similar, and timelines adhere to NCQA and state standards. Finally, the percentage of MH/SUD drugs subject to Step Therapy (10%) is slightly higher than the percentage of M/S drugs subject to Step Therapy (5%), though a fewer number of MH/SUD drugs require Step Therapy vs M/S drugs and, overall, very few drugs in general require Step Therapy. Moreover, given that MH/SUD drugs have a lower denial rate (6%) compared to the step therapy denial rate for M/S drugs (12.2%), the data demonstrates that a higher percentage of step therapy requests are approved for MH/SUD drugs. Therefore, MH/SUD drugs are not being treated more stringently compared to M/S drugs.

Express Scripts conducts routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) testing and is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Corrective action is initiated if a score falls below 95%. As described previously in Step 4, IRR scores for both M/S and MH/SUD classifications were above 98%. These very high scores support that exception criteria is clear & easy to follow, and also that reviews are being conducted consistently for both classifications of prescription drugs.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Step Therapy to MH/SUD drugs, *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 Step Therapy to M/S drugs.

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