NQTL: Formulary Design and Tiering

Classification(s): Pharmacy

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

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

Formulary – Formulary is defined on our website as: "A formulary is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. It may also be referred to as a drug list. Your formulary provides detailed information on what drugs are covered under your pharmacy benefits...".

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

Formulary Tiering: Formulary tiering refers to the placement of particular drug products on various cost-sharing tiers, ranging from 1 to 3.

Wellfleet uses the following formulary tiers:

- Tier 1 (preferred generics): Lowest copayment for select drugs that offer the greatest value compared to other drugs used to treat similar conditions.
- Tier 2 (non-preferred generics and preferred brands): Medium copayment covers brand name drugs that are generally more affordable or may be preferred compared to other drugs to treat the same conditions. This tier also covers non-preferred generic drugs.
- Tier 3 (non-preferred brands): High copayment covers higher cost brand name drugs.

Specialty drugs fall under the same tiering structure but may subject to a specialty tier copay. Specialty drugs are pharmaceutical, biotech or biological drugs that are used in the management of chronic, orphan or rare diseases and have a monthly cost > $670 for a 30-day supply. These injectable or non-injectable medications may possess more than one of the following attributes: Requires specialized storage, distribution, and/or handling; Frequent dosing adjustments and clinical monitoring to decrease potential for drug toxicity and improve clinical outcomes; Involves additional patient education, adherence, and/or support; May include generic or biosimilar products; and/or limited or exclusive drug distribution restrictions. These drugs are denoted on the formulary by "SP".

Identify the Plan's formulary:[2]

Please see www.wellfleetrx.com/students/formularies

[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.

Step 2 – Identify the factors used to determine how the Plans designs its formulary for mental health or substance use disorder and medical/ surgical drugs[3]	
Medical/Surgical: Factors for determining formulary placement and tiering include: 1. Availability of Cost-Effective alternatives 2. High variability in cost within drugs in a given therapeutic class 3. Member Impact (this factor is used only to determine when a negative shift in formulary placement or tiering should be applied) ***Use of Factors – Formulary Design*** For determining formulary design (i.e. inclusion on the formulary) the P&T committee first assesses the clinical efficacy and availability of cost effective alternative as described in Factor 1. Then, the Value Assessment Committee will assess the Cost as described in Factor 2 and makes a recommendation for final determination for inclusion on the formulary. In determining whether to remove a drug from the formulary, the VAC considers Factor 3 (in light of the committees analysis of Factors 1 and 2) for final determination. ***Use of Factors – Formulary Tiering*** For determining formulary tiering (i.e. which tier a drug is assigned to on the formulary), the P&T committee assesses Factors 1 and 2 to determine where the drug should be assigned, and makes a recommendation to the Value Assessment Committee for final determination. If the committee is considering moving the drug to a higher-cost tier, then Factor 3 is considered (in light of the committee's findings on Factors 1 and 2) to determine whether member impact cuts against assigning that particular drug to a higher cost tier. A recommendation is then made by the Value Assessment Committee for final approval.	**MH/SUD**: Factors for determining formulary placement and tiering include: 1. Availability of Cost-Effective alternatives 2. High variability in cost within drugs in a given therapeutic class 3. Member Impact (this factor is used only to determine when a negative shift in formulary placement or tiering should be applied) ***Use of Factors – Formulary Design*** For determining formulary design (i.e. inclusion on the formulary) the P&T committee first assesses the clinical efficacy and availability of cost effective alternative as described in Factor 1. Then, the Value Assessment Committee will assess the Cost as described in Factor 2 and makes a recommendation for final determination for inclusion on the formulary. In determining whether to remove a drug from the formulary, the VAC considers Factor 3 (in light of the committees analysis of Factors 1 and 2) for final determination. ***Use of Factors – Formulary Tiering*** For determining formulary tiering (i.e. which tier a drug is assigned to on the formulary), the P&T committee assesses Factors 1 and 2 to determine where the drug should be assigned, and makes a recommendation to the Value Assessment Committee for final determination. If the committee is considering moving the drug to a higher-cost tier, then Factor 3 is considered (in light of the committee's findings on Factors 1 and 2) to determine whether member impact cuts against assigning that particular drug to a higher cost tier. A recommendation is then made by the Value Assessment Committee for final approval.
Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Formulary Design to mental health or substance use disorder benefits and medical or surgical benefits.	
Medical/Surgical: Factor 1: Availability of Cost-Effective alternatives o **Source**: First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines (through the AMA, APA, ASAM, ACC, etc., or within the PubMed from NIH), peer-reviewed medical literature (within the PubMed from NIH) 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	**MH/SUD**: • Factor 1: Availability of Cost-Effective alternatives o **Source**: First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines (through the AMA, APA, ASAM, ACC, etc., or within the PubMed from NIH), peer-reviewed medical literature (within the PubMed from NIH) 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

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

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 between the two medications, the lower cost option is the 'cost-effective alternative'. 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 2: 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 anything over $670/month supply. Also taken into account are the availability of alternate therapies (brand/generic) & lowest total net cost for course of therapy for given conditions. If the drug is considered to have a high variability in cost, the VAC makes a recommendation for assignment to preferred or non-preferred tiers based on its evaluation of comparative net cost, comparing to other drugs in those tiers. ▪ **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 3: Member Impact (this factor is used only to determine when a negative shift in formulary placement or tiering should 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 either removing a drug product from formulary or shifting from 'preferred' tier to 'non-preferred'. This is only taken into account to decide *not* to apply a negative shift for members. If both factors 1 & 2 suggest removing a drug product from formulary or shifting from 'preferred' tier to 'non-preferred', but there would be a large member impact, we would put the interest of our members first and not make changes.	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 between the two medications, the lower cost option is the 'cost-effective alternative'. 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▪ **Source for Evidentiary Standard:** Internal paid claims data from Express Scripts, excluding reversed claims	▪ **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.	
Timelines/ frequency of review: • Formulary design and tiering are analyzed semi-annually, unless otherwise prohibited by state law. *Formulary Tiering Designation Process:* • The P&T Committee reviews all newly approved drugs and newly-approved indications and dosage forms for formulary status and recommendations for utilization management. The P&T Committee make recommendations for the final version of the formulary and related documents. • The P&T Committee documents are presented to the health plan Value Assessment Committee (VAC). The VAC is tasked to maintain and approve recommended changes to the formulary, drug prior authorization guidelines, and any programs/procedures that affect the utilization of drugs. For formulary decisions on drugs used to treat mental health or substance use disorders, the P&T Committee utilizes appropriate experience and knowledge in treating patients with the specific disease state. The P&T Committee has at least one member in the psychiatry specialty. VAC Committee meetings are held at least semi-annually. First the VAC committee reviews the P&T Committee recommendation, then the VAC Committee makes a final clinical decision. • The VAC reviews the clinical decision and evaluates financial and operational impacts to make final determinations for formulary placement. • Finally, this final formulary placement decision is reviewed by the health plan VAC committee to confirm alignment with clinical decisions. *Formulary Design Management:* • Tiered drug formularies involve groupings of drugs subject to different levels of cost-sharing which are referred to as Tiers. The Student Formulary is a three-tier benefit	*Timelines/ frequency of review:* • Formulary design and tiering are analyzed semi-annually, unless otherwise prohibited by state law. *Formulary Tiering Designation Process*: • The P&T Committee reviews all newly approved drugs and newly-approved indications and dosage forms for formulary status and recommendations for utilization management. The P&T Committee make recommendations for the final version of the formulary and related documents. • The P&T Committee documents are presented to the health plan Value Assessment Committee (VAC). The VAC is tasked to maintain and approve recommended changes to the formulary, drug prior authorization guidelines, and any programs/procedures that affect the utilization of drugs. For formulary decisions on drugs used to treat mental health or substance use disorders, the P&T Committee utilizes appropriate experience and knowledge in treating patients with the specific disease state. The P&T Committee has at least one member in the psychiatry specialty. VAC Committee meetings are held at least semi-annually. First the VAC committee reviews the P&T Committee recommendation, then the VAC Committee makes a final clinical decision. • The VAC reviews the clinical decision and evaluates financial and operational impacts to make final determinations for formulary placement. • Finally, this final formulary placement decision is reviewed by the health plan VAC committee to confirm alignment with clinical decisions. Formulary Design Management: • Tiered drug formularies involve groupings of drugs subject to different levels of cost-sharing which are referred to as Tiers. The Student Formulary is a three-tier benefit design,

design, where the member shares the cost of prescription drug therapy at three levels of copayment. In most instances, generically available drugs will be covered under the first or lowest copay tier, branded drugs listed on the Formulary will be covered under the second copay tier, and branded drugs not on the Formulary will be covered under the third or highest copay tier. *Formulary Development & Maintenance Process (Role of P&T Committee):* • The process, strategies, and evidentiary standards used in applying Formulary Design and tiering are the same for both MH/SUD and M/S drugs, as written. The factors identified in Step Two and the sources identified in Step Three apply equally to MH/SUD and M/S drugs. • Additionally, to become members of the P&T Committee, the physicians must be board certified licensed physicians or pharmacists with over 5 years of practicing in their respective fields. We use the clinical expertise of the P&T Committee members along with published clinical guidelines and scientific evidence to achieve consensus in order to set Formulary recommendations. • As written, Formulary Design processes are the same for both M/S and MH/SUD drugs. The Formulary Management Policy is applied equally to both types of drugs and is reviewed annually for biased verbiage by the Director of Clinical Programs, Clinical Pharmacist, and Chief Medical Officer, and any updates required are made. The current formulary management policy states: o "In order to comply with the Mental Health Parity and Addiction Equity Act (MHPAEA) and other applicable mental health parity laws, no aspect of the Formulary design, including tiering and UM decisions, shall be based on policies, processes, and operations that are more stringent for medications used to treat mental health conditions and substance use disorders (MH/SUD) as compared to medications used to treat medical or surgical conditions. At least annually, Wellfleet and [P&T Vendor] will complete analysis on the Non-Quantitative Treatment Limitations (NQTLs) that apply to the Formulary, which includes identifying each NQTL, identifying the factors considered in the design of the NQTLs, identifying the sources used to define the factors considered in the design of the NQTLs, and analyzing whether the processes, strategies, and evidentiary standards used in applying the NQTLs are comparable and no more stringently applied to medications used to treat MH/SUD conditions as compared to medications used to treat medical or surgical conditions, as written and in operation." o 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,	where the member shares the cost of prescription drug therapy at three levels of copayment. In most instances, generically available drugs will be covered under the first or lowest copay tier, branded drugs listed on the Formulary will be covered under the second copay tier, and branded drugs not on the Formulary will be covered under the third or highest copay tier. Formulary Development & Maintenance Process (Role of P&T Committee): • The process, strategies, and evidentiary standards used in applying Formulary Design and tiering are the same for both MH/SUD and M/S drugs, as written. 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Drugs included in MHSUD: 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. 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.	**Drugs included in MHSUD:** 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. 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.
• The same Non-Formulary Exceptions policy is used for all medication classifications to provide medical necessity overrides of formulary status. This policy, entitled 'Excluded Formulary Drug Exception Criteria', is reviewed at least annually by the Pharmacy and Therapeutics Committee and approved. An annual audit is also conducted to ensure that the policy does not have differences in intent between classifications of medications. To date, no instances of verbiage that would require or insinuate discriminatory practices towards MH/SUD medications have been found, as the requirements are the same across the board for all non-formulary medications. The most recent audit found that the exception policy is the same for all classifications, and requires the following information to be granted approval: o Product being requested for either an FDA approved indication or an indication that is considered safe and effective for the diagnosis by peer-reviewed medical literature or standards of medical practice o Patient has met one of the following: ▪ Tried and failed 3 appropriate formulary options, if available. If less than 3, they have tried all formulary options ▪ Has contraindications to all formulary options	• The same Non-Formulary Exceptions policy is used for all medication classifications to provide medical necessity overrides of formulary status. This policy, entitled 'Excluded Formulary Drug Exception Criteria', is reviewed at least annually by the Pharmacy and Therapeutics Committee and approved. An annual audit is also conducted to ensure that the policy does not have differences in intent between classifications of medications. To date, no instances of verbiage that would require or insinuate discriminatory practices towards MH/SUD medications have been found, as the requirements are the same across the board for all non-formulary medications. The most recent audit found that the exception policy is the same for all classifications, and requires the following information to be granted approval: o Product being requested for either an FDA approved indication or an indication that is considered safe and effective for the diagnosis by peer-reviewed medical literature or standards of medical practice o Patient has met one of the following: ▪ Tried and failed 3 appropriate formulary options, if available. If less than 3, they have tried all formulary options ▪ Has contraindications to all formulary options ▪ Provider has given justifications for the absolute clinical need of the requested medication without trial or failure of alternatives

- Provider has given justifications for the absolute clinical need of the requested medication without trial or failure of alternatives
- If the request is for a multi-source brand, the patient has tried & failed the generic alternative or has a contraindication to the generic
- If the request is for a combination product, the provider has given justification that the individual drug products would not be appropriate

Role of the P&T Committee and VAC Committee:

- To become members of the P&T Committee, the physicians must be board certified licensed physicians with over 5 years of experience in their respective fields. P&T is made up of varying specialties that cover a wide range of diagnoses and care settings. Current specialties represented are: family medicine, internal medicine, hematology/oncology pharmacy, psychiatric pharmacy, OB/GYN, psychiatry, oncology, and pulmonology.
- The VAC is composed of internal leadership and key employees at Wellfleet. Membership covers the clinical & pharmacy team, finance team, sales team, and member experience team.
- The P&T committee determines include/exclude/optional formulary status based upon the evidentiary standards set forth in Step 3 without regard as to whether the drug is used to treat a medical condition or a MH/SUD condition. The Value Assessment Committee (VAC), considers the value of drugs by evaluating both factors set forth in Step 3, including net cost, market share, brand and generic pipeline, drug utilization trends and cost effectiveness of clinically similar medications. Based on the recommendations of the P&T Committee, the VAC decides on formulary tiering. The processes, strategies, and evidentiary standards the VAC uses in Formulary Design for MH/SUD drugs are comparable to, and not more stringently applied than, the processes, strategies, and evidentiary standards used in tiering for M/S drugs. The P&T Charter and VAC charter are reviewed at least annually for parity. There is no language indicating a bias towards one classification of drugs of the other, and the same standards (as seen above) are used for both.

Factors influencing non-preferred formulary placement analysis:

- An audit was conducted for a random subset of formulary medications that are put on a non-preferred tier, 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 Formulary Placement

- If the request is for a multi-source brand, the patient has tried & failed the generic alternative or has a contraindication to the generic
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			Factors Utilized for Formulary Placement

Medication Name	Classification	Tier	Availability of Cost-Effective alternatives	High variability in cost within drugs in a given therapeutic class	Member Impact
Eletriptan tablets	M/S	2	X - Naratriptan Rizatriptan Sumatriptan	X - Eletriptan AWP / unit - $62 Naratriptan AWP / unit - $29 Rizatriptan AWP / unit - $33 Sumatriptan AWP / unit - $25	
Fluvastatin Capsule	M/S	2	X - Atorvastatin Simvastatin Rosuvastatin	X - Fluvastatin AWP / unit - $6 Atorvastatin AWP / unit - $4 Simvastatin AWP / unit - $0.50 Rosuvastatin AWP / unit - $2	
Ketoprofen Capsule	M/S	2	X - Diclofenac Ibuprofen Indomethacin	X - Ketoprofen AWP / unit - $25 Diclofenac - AWP / unit - $3 Ibuprofen - AWP / unit - $0.25 Indomethacin - AWP / unit - $0.40	
Levoxyl Tablet	M/S	2	X - Levothyroxine NP Thyroid	X - Levoxyl AWP / unit - $1.50 Levothyroxine AWP / unit - $0.10 NP Thyroid AWP / unit - $1	
Pantoprazole Tablet	M/S	2	X - Esomeprazole Lansoprazole Omeprazole	X - Pantoprazole AWP / unit - $5 Esomeprazole AWP / unit - $0.25 Lansoprazole AWP / unit - $4 Omeprazole AWP / unit - $0.20	
Zafirlukast Tablet	M/S	2	X - Montelukast	X - Zafirlukast AWP / unit - $2 Montelukast AWP / unit - $0.10	
Alprazolam ODT	MH/SUD	2	X - Alprazolam Clonazepam Lorazepam	X - Alprazolam ODT AWP / unit - $2 Alprazolam AWP / unit - $0.75 Clonazepam AWP / unit - $0.85 Lorazepam AWP / unit - $0.65	
Desipramine Tablet	MH/SUD	2	X - Amitriptyline Doxepin Imipramine	X - Desipramine AWP / unit - $2 Amitriptyline AWP / unit - $0.75 Doxepin AWP / unit - $0.85 Imipramine AWP / unit - $0.70	
Fluoxetine Tablet	MH/SUD	2	X - Citalopram Escitalopram Paroxetine	X - Fluoxetine AWP / unit - $3 Citalopram AWP / unit - $2 Escitalopram AWP / unit - $0.25 Paroxetine AWP / unit - $1.50	
Methylphenidate Chew Tablet	MH/SUD	2	X - Amphetamine Salts	X - Methylphenidate Chew AWP / unit - $4.50 Amphetamine Salts AWP / unit -	

Medication Name	Classification	Tier	Availability of Cost-Effective alternatives	High variability in cost within drugs in a given therapeutic class	Member Impact
Eletriptan tablets	M/S	2	X - Naratriptan Rizatriptan Sumatriptan	X - Eletriptan AWP / unit - $62 Naratriptan AWP / unit - $29 Rizatriptan AWP / unit - $33 Sumatriptan AWP / unit - $25	
Fluvastatin Capsule	M/S	2	X - Atorvastatin Simvastatin Rosuvastatin	X - Fluvastatin AWP / unit - $6 Atorvastatin AWP / unit - $4 Simvastatin AWP / unit - $0.50 Rosuvastatin AWP / unit - $2	
Ketoprofen Capsule	M/S	2	X - Diclofenac Ibuprofen Indomethacin	X - Ketoprofen AWP / unit - $25 Diclofenac - AWP / unit - $3 Ibuprofen - AWP / unit - $0.25 Indomethacin - AWP / unit - $0.40	
Levoxyl Tablet	M/S	2	X - Levothyroxine NP Thyroid	X - Levoxyl AWP / unit - $1.50 Levothyroxine AWP / unit - $0.10 NP Thyroid AWP / unit - $1	
Pantoprazole Tablet	M/S	2	X - Esomeprazole Lansoprazole Omeprazole	X - Pantoprazole AWP / unit - $5 Esomeprazole AWP / unit - $0.25 Lansoprazole AWP / unit - $4 Omeprazole AWP / unit - $0.20	
Zafirlukast Tablet	M/S	2	X - Montelukast	X - Zafirlukast AWP / unit - $2 Montelukast AWP / unit - $0.10	
Alprazolam ODT	MH/SUD	2	X - Alprazolam Clonazepam Lorazepam	X - Alprazolam ODT AWP / unit - $2 Alprazolam AWP / unit - $0.75 Clonazepam AWP / unit - $0.85 Lorazepam AWP / unit - $0.65	
Desipramine Tablet	MH/SUD	2	X - Amitriptyline Doxepin Imipramine	X - Desipramine AWP / unit - $2 Amitriptyline AWP / unit - $0.75 Doxepin AWP / unit - $0.85 Imipramine AWP / unit - $0.70	
Fluoxetine Tablet	MH/SUD	2	X - Citalopram Escitalopram Paroxetine	X - Fluoxetine AWP / unit - $3 Citalopram AWP / unit - $2 Escitalopram AWP / unit - $0.25 Paroxetine AWP / unit - $1.50	
Methylphenidate Chew Tablet	MH/SUD	2	X - Amphetamine Salts	X - Methylphenidate Chew AWP / unit - $4.50 Amphetamine Salts AWP / unit -	

			Methylphenidate	$0.50 Methylphenidate AWP / unit - $1	
Temazepam Capsule	MH/SUD	2	X - Alprazolam Clonazepam Lorazepam	X - Alprazolam ODT AWP / unit - $2 Alprazolam AWP / unit - $0.75 Clonazepam AWP / unit - $0.85 Lorazepam AWP / unit - $0.65	
Venlafaxine ER Tablet	MH/SUD	2	X - Duloxetine Venlafaxine	X - Venlafaxine ER AWP / unit - $16 Duloxetine AWP / unit - $7 Venlafaxine AWP / unit - $2	

MHSUD Parity Policy:

- Wellfleet also has a MHSUD Parity Policy that outlines the Annual NQTL Assessment. Express Scripts is responsible for providing data to help support analyses, if and when needed. Express Scripts has complied with all requested information within 2 weeks of the request. Pertinent to Express Scripts, from the policy:
    - "At least annually, Wellfleet and its applicable pharmacy benefit manager(s) and formulary management vendor(s) will complete analyses on the NQTLs that apply to the prescription drug benefit… As part of the analyses, Wellfleet and its applicable pharmacy benefit managers and formulary management vendors will review the following:
        A. The formulary design and utilization management requirements, as follows:
            1. Formulary design, including utilization management requirements, should be reviewed at least semi-annually for parity.
                i) The formulary is updated on a monthly basis so that coverage accurately reflects new national drug codes of covered drugs. These updates do not require additional parity oversight because the scope of what is covered is not impacted through this process.
                ii) Semi-annual formulary changes that result in changes in coverage within drug classes, utilization management requirement changes, new exclusions, and tier changes will be included in the semi-annual review.
            2. The formulary design analysis includes a semi-annual review of percentages of MH/SUD and M/S drugs on each tier and their applicable utilization management requirements for comparability.

			Methylphenidate	$0.50 Methylphenidate AWP / unit - $1	
Temazepam Capsule	MH/SUD	2	X - Alprazolam Clonazepam Lorazepam	X - Alprazolam ODT AWP / unit - $2 Alprazolam AWP / unit - $0.75 Clonazepam AWP / unit - $0.85 Lorazepam AWP / unit - $0.65	
Venlafaxine ER Tablet	MH/SUD	2	X - Duloxetine Venlafaxine	X - Venlafaxine ER AWP / unit - $16 Duloxetine AWP / unit - $7 Venlafaxine AWP / unit - $2	

MHSUD Parity Policy:

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        B. The formulary design and utilization management requirements, as follows:
            1. Formulary design, including utilization management requirements, should be reviewed at least semi-annually for parity.
                i) The formulary is updated on a monthly basis so that coverage accurately reflects new national drug codes of covered drugs. These updates do not require additional parity oversight because the scope of what is covered is not impacted through this process.
                ii) Semi-annual formulary changes that result in changes in coverage within drug classes, utilization management requirement changes, new exclusions, and tier changes will be included in the semi-annual review.
            2. The formulary design analysis includes a semi-annual review of percentages of MH/SUD and M/S drugs on each tier and their applicable utilization management requirements for comparability.

i) A current version of the formulary file containing GTC/STC codes is used for the analysis. Using the GTC/STC indicators, drugs are classified as MH/SUD vs. M/S.
ii) All covered MH/SUD and M/S drugs are categorized by tier and each utilization management (prior authorization, quantity limits, and step therapy).
iii) The review will include a determination of the percentage of MH/SUD and M/S drugs in each tier. In addition, the review will determine the percentage of MH/SUD and M/S drugs that require each utilization management requirement.
iv) Further analysis may need to be performed to (i) validate whether there is a rationale in the percentage differences, (ii) review additional samples, or (iii) review the clinical rationale.

i) A current version of the formulary file containing GTC/STC codes is used for the analysis. Using the GTC/STC indicators, drugs are classified as MH/SUD vs. M/S.
ii) All covered MH/SUD and M/S drugs are categorized by tier and each utilization management (prior authorization, quantity limits, and step therapy).
iii) The review will include a determination of the percentage of MH/SUD and M/S drugs in each tier. In addition, the review will determine the percentage of MH/SUD and M/S drugs that require each utilization management requirement.
iv) Further analysis may need to be performed to (i) validate whether there is a rationale in the percentage differences, (ii) review additional samples, or (iii) review the clinical rationale.

Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Formulary Design for M/S and MHSUD benefits in operation:

- To ensure that the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for M/S drugs, we completed a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to each copay tier. See table below for M/S results.

MedSurg	Tier	% of Products
Y	1	53%
Y	2	17%
Y	3	29%

- To ensure that the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for MH/SUD drugs, in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in formulary design and tiering for M/S drugs, we completed a review of the percentage of drugs in the M/S and MH/SUD classifications that are subject to each copay tier. See table below for MH/SUD results.

MHSUD	Tier	% of Products
Y	1	74%
Y	2	12%
Y	3	14%

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

As written: Wellfleet uses the same formulary tiering decision-making process for M/S and MH/SUD drugs. On a semi-annual basis, drug formulary reviews go through multiple levels of clinical review from the P&T Committee initial evaluation and tiering recommendation to the VAC's final decision. The process is heavily clinically driven using the following factors: availability of cost-effective alternatives, high variability in cost within drugs in a given therapeutic class, and member impact. The sources used in assessing whether each factor has been met include First Databank (FDB), FDA Prescribing Information, professionally recognized treatment guidelines, peer-reviewed medical literature. Moreover, the sources and evidentiary standards used are the same regardless of the drug's MH/SUD or M/S status. An audit was performed to ensure parity, which showed that 100% of sampled M/S and 100% of MH/SUD medications that were non-preferred on the formulary were impacted by the factors and sources equally. An audit & approval of both the Formulary Management Policy and Excluded Formulary Drug 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, cost-sharing is applied comparably and no more stringently to MH/SUD drugs relative to M/S drugs. We evaluate stringency in operation by analyzing the distribution of M/S and MH/SUD drugs across formulary tiers to ensure that tiering placements are not disproportionately favorable to M/S drugs. Audits performed indicated that Tier 1 (preferred generics) includes a significantly higher percentage of MH/SUD drugs (74% of all formulary MH/SUD drugs) compared to M/S drugs (52% of all formulary M/S drugs). For Tier 2 (non-preferred generics and preferred brands), a lower percentage of formulary MH/SUD drugs are available (12%) compared to formulary M/S drugs (17%), however, the lower percentage of preferred brand MH/SUD drugs is explained by the disproportionately high rate of availability of MH/SUD generic drugs. Tier 3 (non-preferred brands) includes a significantly lower percentage of MH/SUD drugs (15% of all formulary MH/SUD drugs) compared to the percentage of M/S drugs (31% of all formulary M/S drugs).

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

Conclusion: Both as written and in operation the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply Formulary Design and Tiering to M/S benefits in the prescription drug classification. Therefore, the plan finds that the comparative analysis demonstrates its Formulary Design and Tiering practices are compliant with MHPAEA.