NQTL: Quantity Limits

Classification(s): Pharmacy

Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Quantity Limits 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]

Quantity Limit is defined in the Wellfleet Rx Student Formulary as: "Coverage may be limited to specific quantities per prescription and/or time period."

Quantity Limits restrict the amount dispensed per Prescription Order or Refill and/or the amount dispensed per month's supply and are applied to ensure members receive clinically appropriate and medically necessary drugs.

Wellfleet delegates the act of Utilization Review to Express Scripts (ESI), however the application of the Quantity Limit 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). Quantity Limit is defined, in the Wellfleet Pharmacy and Therapeutics Committee Policy, as "Quantity Limit: A limitation on the amount dispensed per Prescription Order or Refill and/or the amount dispensed per month's supply".

Identify the M/S drugs for which Quantity Limits are required:[2]	***Identify the MH/SUD drugs for which Quantity Limits are required***:[3]
Quantity Limits are applicable to some, but not all, M/S drugs. Please see attached (Covered Services Attachment) which details benefits subject to QL	Quantity Limits are applicable to some, but not all, MH/SUD drugs. Please see attached (Covered Services Attachment) which details benefits subject to QL

Step 2 – Identify the factors used to determine that Quantity Limits 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 Quantity Limit or not: 1. Safety - This factor carries more weight due to the member safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance. 2. Anticipated excessive utilization 3. Member Impact (this factor is used only to determine when QL should not be applied)	Factors for determining whether a prescription drug product will have Quantity Limit or not: 1. Safety - This factor carries more weight due to the member safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance. 2. Anticipated excessive utilization 3. Member Impact (this factor is used only to determine when QL 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 formulary design.	**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 formulary design.
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 Quantity Limits to mental health or substance use disorder benefits and medical or surgical benefits.	

Medical/Surgical:
 	
• Factor 1: Safety - This factor carries more weight due to the member safety concerns. Ensuring the safety and wellbeing of our members is of upmost importance.
  o **Source**: 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.
  o **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. The threshold for 'safety' as a factor for a quantity limit will be met if any of the following apply for the medication being reviewed: FDA lists a maximum recommended dose in labeling information, there is a Black Box Warning present on the labeling information, there are two or more serious adverse effects listed in the labeling information, there is a toxicity or poisoning potential.
  ▪ Source for Evidentiary Standard: New Drug Reviews & Therapeutic Class Reviews, P&T Minutes, FDA Labeling sections entitled 'Dosage and Administration', 'Contraindications', 'Warnings & Precautions', 'Adverse Reactions', 'Drug Interactions', 'Use in Specific Populations', and 'Overdosage'
• Factor 2: Anticipated excessive utilization
  o **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
	MH/SUD:
	
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	• Factor 2: Anticipated excessive utilization
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recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.

- **Evidentiary Standard**: Wellfleet's Clinical Pharmacist performs reviews of 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, or utilization of multiple unit doses to equal a total dosage that is commercially available (e.g. utilizing two 10mg tablets to get a single 20mg dose). The factor of Anticipated Excessive Utilization will indicate the necessity of a quantity limit if 10% or more of examined claims are above the threshold set by FDA prescribing information, dosing schedules, etc. In the instance of a medication not having internal claims history, or for new to market medications, the description of a maximum recommended dosage on the FDA labeling information or dosing schedule would indicate the necessity for a quantity limit. This limit would mirror the recommendations in the labeling information. If the Clinical Pharmacist determines a drug is subject to potential excessive utilization, the Clinical Pharmacist or the P&T Committee may recommend applying a quantity limit 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 such limitation.
  - 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 QL should not be applied)
  - **Source**: Internal claims data, internal market and competitive analysis
  - **Evidentiary Standard**: The Value Assessment Committee reviews a cost report for the past year to determine the impact and number of members that may be using a particular benefit that is being considered for QL application. The VAC determines the number of members that will be negatively impacted by quantity limit additions. The VAC makes a decision based on their professional judgement as to whether QL should not be applied to avoid negative member impact. This is only taken into account to decide *not* to apply or to remove a quantity limit requirement from a medication and is not used in the application process for QL. If factors 1 and 2 suggest the addition of QL, but we anticipate significant member or client impact based on our covered demographic, we may put the interest of our members first and not assign a QL designation. Threshold for 'negative member impact' is 5% of total membership utilizing the product that a quantity limit is being considered for.

recognized Compendia - Truven Health Analytics Micromedex DrugDEX (DrugDEX), and peer-reviewed medical literature.

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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 and deadlines, frequency of review: • Turnaround times for review and either approving or denying a QL exception request are based on state requirements. However, on average across Wellfleet's book of business QL exception requests are processed within 1 business day. • Authorizations for both M/S and MHSUD 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. • 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 Quantity Limit Exceptions 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. *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 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 off of the clinical merits of the drug, not the classification of drug itself. Quantity Limit 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	*Timelines and deadlines, frequency of review:* • *Turnaround times for review and either approving or denying a QL exception request are based on state requirements. However, on average across Wellfleet's book of business QL exception requests are processed within 1 business day.* • *Authorizations for both M/S and MHSUD 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.* • *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 Quantity Limit Exceptions 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.* *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 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 off of the clinical merits of the drug, not the classification of drug itself. Quantity Limit 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.

- The most recent review of the Formulary Management 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.
  - • **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

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Relevant Decision Making Committees

- *P&T Committee*

• 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 appropriate quantities/dosing. The Value Assessment Committee (VAC) follows the P&T Committee recommendations to finalize any quantity limit 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 designated 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. The VAC shall use clinical notes from P&T, along with other sources listed above, to make quantity limit determinations.
 	
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 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:
• If a prescription exceeds the designated quantity limit, the filling pharmacy will be issued a denial. If the member and provider elect to request an exception, they will be asked to submit documentation in support of use of the product. The exact process can be seen in Wellfleet's PA guideline packet at
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www.Wellfleetrx.com/formularies. This process is the same for both M/S and MH/SUD drugs. This exception policy is also reviewed in order to determine whether there is any verbiage that would cause decisions regarding exceptions to the application of quantity limits 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 quantity limits. The exceptions policy currently requires one of three main points for approval, none of which are biased toward M/S or MH/SUD drugs:

- There is at least one piece of medical literature supporting the quantity requested and the quantity allowed under the formulary has been ineffective in treating the condition per the providers judgement OR
- Based on clinical evidence and medical literature, the known relevant physical or mental characteristics of the member, and the known characteristics of the drug regimen, the lower quantity is likely to be ineffective OR
- Patient is currently on the requested dose and no higher dosage strength can be used to achieve the same total daily dose

Interrater Reliability Scores

- Interrater Reliability (IRR) analyses are conducted by Express Scripts on a semi-annual basis. Most recent Interrater reliability results for reviews performed were 98.48% for M/S reviews and 99.24% for MH/SUD reviews. There have been no instances of an IRR under 95%. If either classification dropped below the 95% threshold, a corrective action plan would be created and followed by the PBM to ensure compliance.

Factors influencing Quantity Limit Determination analysis:

- An audit was conducted for a random subset of formulary medications that have a quantity limit 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 safety concerns. One product from each classification showed excessive utilization, passing the threshold for anticipated excessive utilization in the future. All safety concerns were sourced from the FDA approved labeling information, and all claims data were sourced from internal databases of paid claims.

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			Factors Utilized for Quantity Limit Application		
Medication Name	**Classification**	**Quantity Limit**	**Safety**	**Anticipated Excessive Utilization**	**Member Impact**
Aripiprazole	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 15mg/day	X - 12% of claims utilizing greater than 15mg / day	
Atomoxetine	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 100mg/day		
Clozapine	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 900mg/day		
Eszopiclone	MH/SUD	X	X - Severe adverse effects, max dose of 3mg/day		
Modafinil	MH/SUD	X	X - Serious adverse effects, max dose of 200mg/day		
Paliperidone	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 12mg/day		
Accutane	MS	X	X - Black box warning, Severe adverse effects, max dose of 200mg/day	X – 11% of claims utilizing multiple dosages to equal one daily dose that is commercially available	

			Factors Utilized for Quantity Limit Application		
Medication Name	**Classification**	**Quantity Limit**	**Safety**	**Anticipated Excessive Utilization**	**Member Impact**
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Atomoxetine	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 100mg/day		
Clozapine	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 900mg/day		
Eszopiclone	MH/SUD	X	X - Severe adverse effects, max dose of 3mg/day		
Modafinil	MH/SUD	X	X - Serious adverse effects, max dose of 200mg/day		
Paliperidone	MH/SUD	X	X - Black box warning, Severe adverse effects, max dose of 12mg/day		
Accutane	MS	X	X - Black box warning, Severe adverse effects, max dose of 200mg/day	X – 11% of claims utilizing multiple dosages to equal one daily dose that is commercially available	

Clopidogrel	MS	X	X - Black box warning, Severe adverse effects, max dose of 75mg/day		
Everolimus	MS	X	X - Severe adverse effects, max dose of 10mg/day		
Glyxambi	MS	X	X - Severe adverse effects, max dose of 25/5mg/day		
Oxycodone-Acetaminophen	MS	X	X - Black box warning, Severe adverse effects, max dose of 60mg/day oxycodone, 4g/day acetaminophen		
Timolol	MS	X	X - Max dose 1 drop/day		

Clopidogrel	MS	X	X - Black box warning, Severe adverse effects, max dose of 75mg/day		
Everolimus	MS	X	X - Severe adverse effects, max dose of 10mg/day		
Glyxambi	MS	X	X - Severe adverse effects, max dose of 25/5mg/day		
Oxycodone-Acetaminophen	MS	X	X - Black box warning, Severe adverse effects, max dose of 60mg/day oxycodone, 4g/day acetaminophen		
Timolol	MS	X	X - Max dose 1 drop/day		

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

To ensure that the processes, strategies, evidentiary standards, and other factors used to apply quantity limit 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 quantity limit to M/S drugs, QL 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 a quantity limit. See table below for M/S results.

To ensure that the processes, strategies, evidentiary standards, and other factors used to apply quantity limit 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 quantity limit to M/S drugs, QL 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 a quantity limit. See table below for MH/SUD results.

M/S QL Requirements	
Total M/S Drugs	8,400
Total M/S Drugs Requiring QL	1,886
QL Required Rate	23%

MH/SUD QL Requirements	
Total MH/SUD Drugs	783
Total MH/SUD Drugs Requiring QL	309
QL Required Rate	39%

- We also completed an analysis of the turnaround times for QL exception 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 quantity limit exceptions in calendar year 2023. Results can be seen in the table below.

Global M/S QL Analysis	
Total QL Requests	558
Total QL Approvals	377
Total QL Denials	181
QL Approval Rate	67%
QL Denial Rate	33%
Average Turnaround Time	0.5 Calendar Days

- Although the percentage of MH/SUD drugs is slightly higher than the M/S drugs, the selection process of drugs for the QL NQTL are still considered comparable to that for M/S drugs. The factors and sources used are the same for both MH/SUD and M/S drugs. One reason for the higher percentage seen in the MH/SUD drugs is due to safety concerns. MH/SUD drugs can have serious side effects, and many have potential for abuse, so quantity limits would help ensure patients are not taking more than what is approved by the FDA. Some examples of these limits, from the FDA labeling information, are below:
    - Atomoxetine: Initial dose: 40 mg ; Target dose: 80 mg ; **Maximum Total Dose: 100 mg**
    - Symbyax: **The safety of doses above 18 mg per 75 mg has not been evaluated in clinical studies.**
    - Olanzapine: **Olanzapine is not indicated for use in doses above 20mg/day**
    - Belsomra: **The maximum recommended dose of Belsomra is 20 mg taken no more than once per night.**
    - Clozapine: **Maximum daily dose: 900 mg**
- Many drugs in the M/S class have similar concerns, but since the M/S category is so broad, it is a much smaller percentage compared to the MH/SUD category. This is mainly due to dilution of the class by products like OTC's, weight-based dosing antibiotics, antivirals, and antifungals, supplements, and compounding supplies. These products, generally, are very safe and require modified dosing based on many different patient specific variables. There are also many more subcategories

within the M/S class compared to the MH/SUD class of drugs. Many of those subcategories do not or rarely have Quantity Limit edits (i.e. Allergenic Extracts, Antidotes, Detergents, Diagnostic Agents, etc.). Also, the much smaller percentage of the total medications in the MH/SUD category skews the percentage of applied QL. 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. Lastly, an effort was recently conducted (early 2024, after this time period being reviewed), to remove any quantity limits that may be construed as 'red-tape' for our members. In total, 37 QL's were removed from MH/SUD medications.

- We also completed an analysis of the turnaround times for QL exception 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 quantity limit exceptions in calendar year 2023. Results can be seen in the table below.

Global MH/SUD QL Analysis	
Total QL Requests	173
Total QL Approvals	91
Total QL Denials	82
QL Approval Rate	53%
QL Denial Rate	47%
Average Turnaround Time	0.6 Calendar Days

- Since the percentage of Denials is higher in the MH/SUD classification, an audit was performed to ensure parity. 25% of denials were examined to ensure that they were true denials and met intent. All of the 21 denials were upheld after audit, and were originally denied due to the following reasons: Requested dosage over FDA recommended 'max' without trial and failure of recommended dosage, Requested dosage can be provided as a single strength tablet/capsule (eg Vyvanse 30 mg requested as 2 capsules once daily when a 60 mg strength is available), & Failure to provide medical literature that supports the increased dosage above standard quantity limit

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 quantity limits 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, 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. Quantity limit is imposed on drug products based on the factors presented previously for both classifications of drugs.

Whether to recommend a quantity limit for a drug is based on the drug's safety, anticipated excessive utilization, and member Impact. Whether each factor is met is 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, aggregated data or non-identifiable utilization reports, internal claims data, internal market and competitive analysis. 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 quantity limits is subject to the same review process for both M/S and MH/SUD drugs, and the same reviewers are used for M/S and MH/SUD drug authorization reviews. Authorizations for both M/S and MHSUD 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. Appeals turnaround times are the same for all drugs and are dependent on federal and state regulations to ensure compliance. An audit & approval of the Quantity Limit 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.

Thus, we conclude that the processes, strategies, evidentiary standards, and other factors used to apply Quantity Limits 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 Quantity Limits to M/S drugs.

In Operation: In operation, the percentage of MH/SUD drugs with approved quantity limits is lower than the percentage of M/S drugs requiring with approved quantity limits. The denial rate for MH/SUD drug requests (47%) is higher than the denial rate for M/S drug requests (33%). However, one reason for the higher percentage seen in the MH/SUD drugs is due to safety concerns. MH/SUD drugs can have serious side effects, and many have potential for abuse, so quantity limits would help ensure patients are not taking more than what is approved by the FDA. Some drugs in the M/S class have similar concerns, but since the M/S category is so broad, it is a much smaller percentage compared to the MH/SUD category. There are also many more subcategories within the M/S class compared to the MH/SUD class of drugs. Many of those subcategories do not or rarely have traditionally have Quantity Limit edits (i.e. Allergenic Extracts, Antidotes, Detergents, Diagnostic Agents, etc.). Wellfleet reviewed the data and associated claims and determined that the application of quantity limits and denial rates were clinically appropriate subject to the factors, sources, and evidentiary standards identified in Step 3. Also, the percentage of total M/S medications is much greater (91.5%) compared to the percentage of total MH/SUD medications (8.5%). Moreover, federal parity guidance is clear that metrics alone are not indicative of parity non-compliance so long as the plan has investigated the data, the reasons for the underlying data, and has determined that the same processes, strategies, factors and evidentiary standards were applied to MH/SUD and M/S drugs. Wellfleet has done so here, and has determined MH/SUD and M/S drugs were treated comparably.

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 quantity limits 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 quantity limits to M/S drugs.

Conclusion: Both as written and in operation the processes, strategies, evidentiary standards, and other factors used to apply Quantity Limits 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 Quantity Limits to M/S benefits in the prescription drug classification. Therefore, the plan finds that the comparative analysis demonstrates its Quantity Limits practices are compliant with MHPAEA.