

Pharmacy Medical Necessity Guidelines: Non-Opioid Pharmacy Products with Quantity Limitations

Effective: April 8, 2025

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Prior Authorization Required	\checkmark	Type of Review – Care Management			
Not Covered		Type of Review – Clinical Review			\checkmark
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review			RXUM
These pharmacy medical necessity guidelines apply to the following: Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans			Fax Numbers: RXUM: 617.673.0939		

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Tufts Health Together participates in the MassHealth Unified Formulary. The MassHealth Drug List (MHDL) displays pharmacy drug coverage and criteria. Many drugs on the MHDL with quantity limits have specific criteria for exceeding the quantity for the agent in question. However, this is not the case for all pharmacy products. If a product on the MHDL has a quantity limit but does not have accompanying criteria to exceed that limit, then the criteria housed in this Medical Necessity Guideline applies. Please refer to the MHDL.

Note: Tufts Health Together maintains its own quantity limits for opioids. Refer to the Tufts Health Together MNG titled "Opioids and Analgesics" for more information and applicable criteria.

COVERAGE GUIDELINES

The plan may authorize additional quantities for drugs that are restricted under the Quantity Limitations (QL) Program when all of the following criteria for a particular regimen are met and limitations do not apply:

1. Documentation that the quantity of medication needed to clinically manage the member's disease state within a given timeframe is greater than the current quantity limit allowed

AND

2. The requested amount is the minimum necessary therapeutic quantity

LIMITATIONS

- 1. Approval duration will be determined based on the length of approval for the specific drug on the MassHealth Drug List.
- 2. Requests to exceed quantity limits will only be approved for FDA-approved indications or those supported by compendia. Requests to exceed quantity limitations for experimental or investigational use will be denied.

CODES

None

REFERENCES

1. MassHealth Drug List. Available at: https://mhdl.pharmacy.services.conduent.com/MHDL/welcome.do. Accessed March 24, 2025 2.

APPROVAL HISTORY

March 20, 2023: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- 1. January 9, 2024: Effective February 1, 2024, updated RxUM fax number.
- 2. April 8, 2025: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical

Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services