Pharmacy Medical Necessity Guidelines: Non-Sedating Antihistamines

Effective: September 9, 2025

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

FDA-APPROVED INDICATIONS

Desloratadine is indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 6 months of age and older, for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 2 years of age and older, and for the symptomatic relief of pruritus and reduction in the number and size of hives in patients with chronic idiopathic urticaria 6 months of age and older.

Levocetirizine is indicated for the relief of symptoms associated with perennial allergic rhinitis in pediatric patients 6 months to 2 years of age, for the relief of symptoms of seasonal allergic rhinitis in patients 2 years of age and older, and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticarial in patients 6 months of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred non-sedating antihistamine for Members when **ONE** of the following criterions is met and limitations do not apply:

Desloratadine (Clarinex), levocetirizine (Xyzal)

1. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with both a loratadine- and a cetirizine-containing agent.

OR

2. The Member is between 6 months and 2 years of age and has tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with a cetirizine-containing agent.

LIMITATIONS

1. Requests for brand-name products, with AB-rated generics, will also be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Clarinex (desloratadine) [prescribing information]. Jersey City, NJ: Organon & Co, Inc; November 2022 .
2. Xyzal (levocetirizine) [package insert]. Bridgewater, NJ: Sanofi-Aventis; April 2019.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, removed Semprex-D from the MNG due to product discontinuation.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 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