Pharmacy Medical Necessity Guidelines:
Anti-Allergy Medications, Ophthalmic

Effective: May 13, 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

Ophthalmic antihistamines and mast cell stabilizers are indicated for allergic conjunctivitis; for the prevention of itching associated with allergic conjunctivitis or for the treatment of the signs and symptoms of allergic conjunctivitis.

Nonpreferred ophthalmic antihistamines include **azelastine, epinastine, Lastacaft (alcaftadine), and olopatadine 0.1% and 0.2%**

Nonpreferred ophthalmic mast cell stabilizers include **Alocril (nedocromil), Alomide (lodoxamide),** and **Bepreve (bepotastine)**

Ketotifen, nedocromil, and azelastine are approved for patients three years of age and older.

Epinastine, alcaftadine, olopatadine 0.1%, olopatadine 0.2%, lodoxamide, and **bepotastine** are approved for patients two years of age and older.

Cromolyn is approved for patients four years of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of a nonpreferred ophthalmic anti-allergy agent for Members when the following criteria for a particular regimen are met and limitations do not apply:

1. **Member is four years of age and older:** The Member had an inadequate response or adverse reaction to, or the provider indicates clinical inappropriateness of therapy with, the two preferred alternative therapies: cromolyn and ketotifen.
2. **Member is three years of age:** The Member had an inadequate response or adverse reaction to, or the provider indicates clinical inappropriateness of therapy with, ketotifen.
3. **Member is two years of age:** The request is for epinastine, alcaftadine, olopatadine 0.1%, olopatadine 0.2%, lodoxamide, or bepotastine.

LIMITATIONS

1. Duration of initial approval is one year. Initial and reauthorization requests are reviewed against the same criteria.
2. Requests for brand-name products, which have AB-rated generics, will also be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Alocril (nedocromil) [prescribing information]. Madison, NJ: Allergan, Inc.; June 2018.
2. Alomide (lodoxamide) [prescribing information]. East Hanover, NJ: Novartis; August 2020.
3. American Optometric Association. Optometric Clinical Practice Guideline: Care of the Patient with Conjunctivitis. St. Louis, MO. November 2002.
4. Azelastine [prescribing information]. Hollywood, FL: Somerset Therapeutics, LLC; December 2019.
5. Bepreve (bepotastine) [prescribing information]. Tampa, FL: Bausch & Lomb Inc.; August 2022.
6. Bilkhu, PS, et al. Effectiveness of Nonpharmacologic Treatments for Acute Seasonal Allergic Conjunctivitis. Ophthalmology 2014; 12:72-78.

7. Epinastine [prescribing information]. Berlin, CT: Breckenridge Pharmaceutical, Inc.; November 2021.
8. Lastacaft (alcaftadine) [prescribing information]. Madison, NJ: Allergan, Inc.; June 2020.
9. Olopatadine 0.2% [prescribing information]. Sunrise, FL: Cipla USA, Inc.; December 2018.
10. Pataday (olopatadine) [prescribing information]. Fort Worth, TX: Alcon; December 2020.

APPROVAL HISTORY

October 11, 2022: Reviewed by the Pharmacy and Therapeutics Committee

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective November 1, 2023, updated length of approval to one year. Removed emedastine from MNG due to product discontinuation. Added olopatadine 0.1% that will be approved for members two years of age.
2. May 14, 2024: Effective August 1, 2024 updated RxUM fax number and previous trial language.
3. May 13, 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