

Pharmacy Medical Necessity Guidelines: Anti-Allergy Medications, Ophthalmic

Effective: January 12, 2021

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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<p>Fax Numbers: RXUM: 617.673.0988</p>	

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, Emadine (emedastine), Lastacaft (alcaftadine), and olopatadine 0.1% and 0.2%

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

Ketotifen, nedocromil, olopatadine 0.1%, emedastine, and azelastine are approved for patients three years of age and older.

Epinastine, alcaftadine, 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:

- Member is four years of age and older:** The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with the two preferred alternative therapies: cromolyn and ketotifen.
- Member is three years of age:** The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with ketotifen.
- Member is two years of age:** The request is for epinastine, alcaftadine, olopatadine 0.2%, lodoxamide, or bepotastine.

LIMITATIONS

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

CODES

None

REFERENCES

1. Bepreve (bepotastine) [prescribing information]. Bridgewater, NJ: Bausch + Lomb; September 2019.
2. Azelastine [prescribing information]. Somerset, NJ: Somerset Therapeutics, LLC; April 2019.
3. Lastacaft (alcaftadine) [prescribing information]. Madison, NJ: Allergan, Inc.; June 2020.
4. Patanol (olopatadine) [prescribing information]. Fort Worth, TX: Alcon; April 2018.
5. Pataday (olopatadine) [prescribing information]. Fort Worth, TX: Alcon; February 2020.
6. Alocril (nedocromil) [prescribing information]. Madison, NJ: Allergan, Inc.; June 2018.
7. Alomide (Iodoxamide) [prescribing information]. East Hanover, NJ: Novartis; August 2020.
8. Emadine (emedastine) [prescribing information]. Fort Worth, TX: Alcon; August 2002.
9. Torkildsen G, et al. The safety and efficacy of alcaftadine 0.25% ophthalmic solution for the prevention of itching associated with allergic conjunctivitis. *Curr Med Res Opin.* 2011;27(3):623-631.
10. Greiner J, et al. Evaluation of alcaftadine 0.25% ophthalmic solution in acute allergic conjunctivitis at 15 minutes and 16 hours after instillation versus placebo and olopatadine 0.1%. *J Clin Opth* 2011;5:87-93.
11. Bilkhu, PS, et al. Effectiveness of Nonpharmacologic Treatments for Acute Seasonal Allergic Conjunctivitis. *Ophthalmology* 2014; 12:72-78.
12. American Optometric Association. *Optometric Clinical Practice Guideline: Care of the Patient with Conjunctivitis.* St. Louis, MO. November 2002.

APPROVAL HISTORY

June 4, 2014: Reviewed by the Pharmacy and Therapeutics Committee

Subsequent endorsement date(s) and changes made:

1. March 10, 2015: Criterion for approval if diagnosed with a chronic condition was removed; approval duration is limited to one year.
2. September 16, 2015: Approval duration approved for life of plan.
3. January 1, 2016: Administrative change to rebranded template.
4. January 12, 2106: No changes.
5. January 10, 2017: Reflected generic availability of Patanol (olaptadine 0.1%).
6. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
7. January 9, 2018: Administrative update. Reflected the generic availability of Pataday 0.02%.
8. January 8, 2019: Effective 1/14/19, updated criteria to account for age indications of nonpreferred agents. Administrative changes made to template.
9. January 14, 2020: No changes.
10. January 12, 2021: 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](#)