

STEP THERAPY POLICY

- POLICY:** Ophthalmic Anti-Allergics – Miscellaneous Step Therapy Policy
- Alex® (loteprednol etabonate 0.2% ophthalmic suspension – Bausch & Lomb)
 - azelastine hydrochloride 0.05% ophthalmic solution (generic only)
 - Bepreve® (bepotastine besilate 1.5% ophthalmic solution – Bausch & Lomb, generic)
 - epinastine hydrochloride 0.05% ophthalmic solution (generic only)
 - Lastacast® (alcaftadine 0.25% ophthalmic solution – Allergan)
 - olopatadine hydrochloride 0.2% ophthalmic solution (generic only)
 - olopatadine hydrochloride 0.1% ophthalmic solution (generic only)
 - Zerviate™ (cetirizine 0.24% ophthalmic solution – Eyevance)

REVIEW DATE: 01/25/2023

OVERVIEW

All of the ophthalmic anti-allergic agents are generally indicated for the treatment of allergic conjunctivitis.²⁻⁹ Table 1 provides mechanism of action, indication, and dosing information for the ophthalmic anti-allergic products. Of note, in 2020, all of the prescription olopatadine products had their FDA-approval switched from prescription to over-the-counter (OTC) status.¹⁴ Therefore, prescription brand olopatadine products are no longer available, but prescription generic olopatadine products are still currently on the market. The OTC olopatadine products are not targeted in this policy. In December of 2021, Lastacast's FDA-approval was also switched from prescription to OTC status. However, OTC Lastacast is also not targeted in this policy.

Table 1. Ophthalmic Anti-Allergics (by Mechanism of Action).²⁻⁹

Brand (generic)	FDA-Approved Indications	Dosing	Indicated Age(s)
Selective H₁-Antagonist			
Zerviate™ (cetirizine 0.24%)	Treatment of ocular itching associated with allergic conjunctivitis.	1 drop into each affected eye BID.	Patients ≥ 2 years of age.
Corticosteroid			
Alex® (loteprednol etabonate 0.2%)	Temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.	1 drop in the affected eye(s) QID.	Patients ≥ 18 years of age.
Selective H₁-Antagonist and Mast Cell Stabilizers (Dual Mechanism)			
azelastine HCl 0.05% (generic)	Treatment of itching of the eye associated with allergic conjunctivitis.	1 drop BID into each affected eye.	Patients ≥ 3 years of age.
bepotastine besilate 1.5% (Bepreve®, generic)	Treatment of itching associated with allergic conjunctivitis.	1 drop in the affected eye(s) BID.	Patients ≥ 2 years of age.
epinastine HCl 0.05% (generic)	Prevention of itching associated with allergic conjunctivitis.	1 drop BID into each eye.	Patients ≥ 2 years of age.
Lastacast® (alcaftadine 0.25%)	Prevention of itching associated with allergic conjunctivitis.	1 drop in each eye QD.	Patients ≥ 2 years of age.
olopatadine HCl 0.1% (generic)†	Treatment of the signs and symptoms of allergic conjunctivitis.	1 drop in each affected eye BID (interval of 6 to 8 hours).	Patients ≥ 3 years of age.
olopatadine HCl 0.2% (generic)†	Treatment of ocular itching associated with allergic conjunctivitis.	1 drop in each affected eye QD.	Patients ≥ 2 years of age.

H₁ – Histamine-1; BID – Twice daily; QID – Four times daily; QD – Once daily; † Over-the-counter product available, but not targeted in this policy.

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Guidelines

The Conjunctivitis Preferred Practice Pattern (2018) and Cornea/External Disease Summary Benchmarks (2022) recommend treating mild allergic conjunctivitis with an OTC antihistamine/vasoconstrictor combination product or with an ophthalmic H₁-receptor antagonist.^{1,13} In frequently recurrent or persistent cases, mast cell stabilizers may be utilized; combination antihistamine/mast cell stabilizers may also be used to treat either acute or chronic disease. A short course of ophthalmic corticosteroids can be added to the regimen if the symptoms are not adequately controlled.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Note: OTC Pataday and OTC Lastacaft products are not targeted in this policy.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic azelastine ophthalmic solution, bepotastine besilate 1.5% ophthalmic solution, generic epinastine ophthalmic solution, prescription generic olopatadine 0.1% ophthalmic solution, prescription generic 0.2% olopatadine ophthalmic solution

Step 2: Alex, Bepreve, Lastacaft, Zerviate

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient requires the concurrent use of Alex and an H₁ antagonist (e.g., Zerviate) or an H₁ antagonist/mast cell stabilizer (e.g., azelastine ophthalmic solution, epinastine ophthalmic solution, bepotastine ophthalmic solution [Bepreve, generic], Lastacaft, olopatadine 0.1% ophthalmic solution, olopatadine 0.2% ophthalmic solution), approve Alex.
3. If the patient has tried a different ophthalmic steroid for the current condition, approve Alex.
4. No other exceptions are recommended.

REFERENCES

1. Varu DM, Rhee MK, Akpek EK, et al. for the American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Conjunctivitis Preferred Practice Pattern. *Ophthalmology*. 2019;26(1):94-169.
2. Olopatadine 0.1% ophthalmic solution [prescribing information]. Allendale, NJ: Rising; December 2017.
3. Azelastine hydrochloride ophthalmic solution [prescribing information]. Weston, FL: Apotex; December 2022.
4. Epinastine 0.05% ophthalmic solution [prescribing information]. Hollywood, FL: Somerset; July 2021.
5. Olopatadine 0.2% ophthalmic solution [prescribing information]. Weston, FL: Apotex; December 2022.
6. Bepreve[®] ophthalmic solution [prescribing information]. Tampa, FL: Bausch & Lomb; August 2022.
7. Lastacaft[®] ophthalmic solution [prescribing information]. Irvine, CA: Allergan; June 2020.
8. Alex[®] ophthalmic suspension [prescribing information]. Tampa, FL: Bausch & Lomb; March 2022.
9. Zerviate[™] ophthalmic solution [prescribing information]. Fort Worth, TX: Eyeavance; November 2022.
10. FDA Prescription to Over-the-counter (OTC) Switch List. U.S. Food and Drug Administration Web site. Available at: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/prescription-over-counter-otc-switch-list>. Updated March 17, 2022. Accessed on January 12, 2023.

11. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel, Hoskins Center for Quality Eye Care. Summary benchmarks for preferred practice patten guidelines. Available at: <https://www.aao.org/summary-benchmark-detail/cornea-external-disease-summary-benchmarks-2020>. Updated December 2022. Accessed January 12, 2023.