

STEP THERAPY POLICY

- POLICY:** Ophthalmic Anti-Allergics – Miscellaneous Step Therapy Policy
- Alex® (loteprednol etabonate 0.2% ophthalmic suspension – Bausch & Lomb, generic)
 - 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)
 - Lastacaft® (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)

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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.¹⁰ 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, Lastacaft's FDA-approval was also switched from prescription to OTC status. However, OTC Lastacaft is also not targeted in this policy.

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

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

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

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 Lastacraft 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, generic bepotastine besilate 1.5% ophthalmic solution, generic epinastine ophthalmic solution, prescription generic olopatadine 0.1% ophthalmic solution, prescription generic olopatadine 0.2% ophthalmic solution

Step 2: generic loteprednol etabonate 0.2% ophthalmic suspension, Alrex, Bepreve, Lastacraft, 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 Alrex or generic loteprednol etabonate 0.2% ophthalmic suspension and an H₁ antagonist or an H₁ antagonist/mast cell stabilizer, approve Alrex or generic loteprednol etabonate 0.2% ophthalmic suspension.
Note: An example of an H₁ antagonist is Zerviate. Examples of H₁ antagonist/mast cell stabilizers are azelastine ophthalmic solution, epinastine ophthalmic solution, bepotastine ophthalmic solution [Bepreve, generic], Lastacraft, olopatadine 0.1% ophthalmic solution, and olopatadine 0.2% ophthalmic solution.
3. If the patient has tried a different ophthalmic steroid for the current condition, approve Alrex or generic loteprednol etabonate 0.2% ophthalmic suspension.
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]. Bridgewater, NJ: Alembic; December 2018.
3. Azelastine hydrochloride ophthalmic solution [prescribing information]. Weston, FL: Apotex; December 2022.

02/14/2024

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Ophthalmic Anti-Allergics – Miscellaneous Step Therapy Policy

Page 3

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. Alrex® ophthalmic suspension [prescribing information]. Tampa, FL: Bausch & Lomb; March 2022.
9. Zerviate™ ophthalmic solution [prescribing information]. Fort Worth, TX: Eyevance; 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 February 9, 2024.
11. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel, Hoskins Center for Quality Eye Care. Summary benchmarks for preferred practice pattern guidelines. Available at: <https://www.aao.org/summary-benchmark-detail/cornea-external-disease-summary-benchmarks-2020>. Updated December 2022. Accessed on February 9, 2024.

02/14/2024

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