



STEP THERAPY POLICY

- POLICY:** Ophthalmic Anti-Allergics – Miscellaneous Step Therapy Policy
- Alrex[®] (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)
 - Lastacraft[®] (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: 02/14/2024; selected revision 02/21/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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, Lastacraft's FDA-approval was also switched from prescription to OTC status. However, OTC Lastacraft 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 | | | |
| Alrex® (loteprednol etabonate 0.2%, generic) | 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. |
| Lastacaft® (alcaftadine 0.25%) | Prevention of itching associated with allergic conjunctivitis. | 1 drop in each eye QD. | Patients ≥ 2 years of age. |

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

| Brand (generic) | FDA-Approved Indications | Dosing | Indicated Age(s) |
|--|--|---|----------------------------|
| Selective H₁-Antagonist and Mast Cell Stabilizers (Dual Mechanism) | | | |
| 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.

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.

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, Lastacaft, Zerviate

Ophthalmic Anti-Allergics – Miscellaneous product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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], Lastacaft, 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.

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.
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.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-------------------|--|-------------|
| Annual Revision | No criteria changes. | 01/25/2023 |
| Annual Revision | No criteria changes. | 02/14/2024 |
| Selected Revision | Generic loteprednol etabonate 0.2% ophthalmic suspension was added to Step 2. Regarding the exception criterion in reference to concurrent use of Alrex or generic loteprednol etabonate 0.2% ophthalmic suspension and an H ₁ antagonist or an H ₁ antagonist/mast cell stabilizer, the examples of H ₁ antagonist and H ₁ antagonist/mast cell stabilizers were moved to a Note. There were no other changes to the criteria. | 02/21/2024 |

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