

## STEP THERAPY POLICY

- POLICY:** Ophthalmic Anti-Allergics – Miscellaneous Step Therapy Policy
- Alrex® (loteprednol etabonate 0.2% ophthalmic suspension – Bausch & Lomb/Valeant)
  - azelastine hydrochloride 0.05% ophthalmic solution (generics only)
  - Bepreve® (bepotastine besilate 1.5% ophthalmic solution – Bausch & Lomb/Valeant)
  - Elestat® (epinastine hydrochloride 0.05% ophthalmic solution – Allergan, generics [brand discontinued])
  - Emadine® (emedastine difumarate 0.05% ophthalmic solution – Alcon [discontinued])
  - Lastacaft® (alcaftadine 0.25% ophthalmic solution – Allergan)
  - Pataday® (olopatadine hydrochloride 0.2% ophthalmic solution – Alcon, generics [brand discontinued])
  - Patanol® (olopatadine hydrochloride 0.1% ophthalmic solution – Alcon, generics [brand discontinued])
  - Pazeo® (olopatadine hydrochloride 0.7% ophthalmic solution – Alcon [discontinued])
  - Zerviate™ (cetirizine 0.24% ophthalmic solution – Akorn)

**REVIEW DATE:** 01/13/2021

---

### OVERVIEW

All of the ophthalmic anti-allergic agents are generally indicated for the treatment of allergic conjunctivitis.<sup>2-13</sup> Table 1 provides mechanism of action, indication, and dosing information for the ophthalmic anti-allergic products. Of note, Emadine has been discontinued by the manufacturer. Brand Elestat is also no longer marketed; however, generic epinastine products remain on the market. In 2020, all of the prescription olopatadine products had the FDA-approval switched from prescription to over-the-counter (OTC) status.<sup>14</sup> Patanol became OTC Pataday® Twice Daily Relief (olopatadine hydrochloride ophthalmic solution 0.1%); Pataday became OTC Pataday® Once Daily Relief (olopatadine hydrochloride ophthalmic solution 0.2%); and Pazeo became OTC Pataday® Once Daily Relief Extra Strength (olopatadine hydrochloride ophthalmic solution 0.7%). Therefore, prescription brand Patanol, Pataday, and Pazeo are no longer available, but prescription generics olopatadine 0.1% and 0.2% products are still currently on the market. The OTC Pataday products are not targeted in this policy.

**Table 1. Ophthalmic Anti-Allergics (by Mechanism of Action).<sup>2-13</sup>**

Brand (generic)	FDA-Approved Indications	Dosing	Indicated Age(s)
<b>Selective H<sub>1</sub>-Antagonist</b>			
<b>Zerviate™</b> (cetirizine 0.24%)	Treatment of ocular itching associated with allergic conjunctivitis.	1 drop into each affected eye BID.	Patients ≥ 2 years of age.
<b>Emadine®</b> (emedastine difumarate 0.05%)	Temporary relief of the signs and symptoms of allergic conjunctivitis.	1 drop in the affected eye(s) up to QID.	Patients ≥ 3 years of age.
<b>Corticosteroid</b>			
<b>Alrex®</b> (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.

**Table 1 (continued). Ophthalmic Anti-Allergics (by Mechanism of Action).<sup>2-13</sup>**

Brand (generic)	FDA-Approved Indications	Dosing	Indicated Age(s)
<b>Selective H<sub>1</sub>-Antagonist and Mast Cell Stabilizers (Dual Mechanism)</b>			
<b>azelastine HCl 0.05%</b> (generics)	Treatment of itching of the eye associated with allergic conjunctivitis.	1 drop BID into each affected eye.	Patients ≥ 3 years of age.
<b>Bepreve<sup>®</sup></b> (bepotastine besilate 1.5%)	Treatment of itching associated with allergic conjunctivitis.	1 drop in affected eye(s) BID.	Patients ≥ 2 years of age.
<b>epinastine HCl 0.05%</b> (Elestat <sup>®</sup> , generics)	Prevention of itching associated with allergic conjunctivitis.	1 drop BID into each eye.	Patients ≥ 2 years of age.
<b>ketotifen 0.025%</b> (Alaway <sup>®</sup> , generics; Zaditor <sup>®</sup> ) [OTC]	Temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.	1 drop in the affected eye(s) BID, every 8 to 12 hours.	Patients ≥ 3 years of age.
<b>Lastacaft<sup>®</sup></b> (alcaftadine 0.25%)	Prevention of itching associated with allergic conjunctivitis.	1 drop in each eye QD.	Patients ≥ 2 years of age.
<b>Pataday<sup>®</sup></b> (olopatadine HCl 0.2%)	Treatment of ocular itching associated with allergic conjunctivitis.	1 drop in each affected eye QD.	Patients ≥ 2 years of age.
<b>olopatadine HCl 0.1%</b> (Patanol <sup>®</sup> , generics)	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.
<b>Pazeo<sup>®</sup></b> (olopatadine HCl 0.7%)	Treatment of ocular itching associated with allergic conjunctivitis.	1 drop in each affected eye QD.	Patients ≥ 2 years of age.

H<sub>1</sub> – Histamine-1; BID – Twice daily; QID – Four times daily; OTC – Over-the-counter; QD – Once daily.

## Guidelines

The 2018 Preferred Practice Pattern on Conjunctivitis from the American Academy of Ophthalmology recommends treating mild allergic conjunctivitis with an OTC antihistamine/vasoconstrictor combination product or with an ophthalmic H<sub>1</sub>-receptor antagonist.<sup>1</sup> 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 topical 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 products are not targeted in this policy.

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

**Step 1:** generic azelastine ophthalmic solution, generic epinastine ophthalmic solution, prescription generic olopatadine 0.1% ophthalmic solution, prescription generic 0.2% olopatadine ophthalmic solution

**Step 2:** Alex, Bepreve, Elestat (discontinued), Emadine (discontinued), Lastacaft, prescription Pataday (discontinued), prescription Patanol (discontinued), prescription Pazeo (discontinued), 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 H<sub>1</sub> antagonist (e.g., Emadine, Zerviate) or an H<sub>1</sub> antagonist/mast cell stabilizer (e.g., azelastine ophthalmic solution, epinastine ophthalmic solution, Bepreve, Lastacaft, olopatadine 0.1% ophthalmic solution, olopatadine 0.2% ophthalmic solution, Pazeo), 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. Patanol<sup>®</sup> solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; September 2019.
3. Azelastine solution [prescribing information]. Lake Forest, IL: Akorn, Inc.; October 2020.
4. Elestat<sup>®</sup> solution [prescribing information]. Irvine, CA: Allergan, Inc.; January 2012.
5. Pataday<sup>™</sup> [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; September 2019.
6. Bepreve<sup>®</sup> solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb, a division of Valeant Pharmaceuticals North America LLC; February 2018.
7. Lastacaft<sup>®</sup> solution [prescribing information]. Irvine, CA: Allergan, Inc.; June 2020.
8. Emadine<sup>®</sup> solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc.; September 2019.
9. Alex<sup>®</sup> suspension [prescribing information]. Bridgewater, NJ: Bausch & Lomb, a division of Valeant Pharmaceuticals North America LLC; August 2019.
10. Zaditor<sup>®</sup> Drug Facts. Fort Worth, TX: Alcon Laboratories, Inc.; October 2020.
11. Alaway<sup>®</sup> Drug Facts. Tampa, FL: Bausch & Lomb Pharmaceuticals, Inc.; January 2020.
12. Pazeo<sup>®</sup> solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; April 2017.
13. Zerviate<sup>™</sup> ophthalmic solution [prescribing information]. Lake Forest, IL: Akorn, Inc.; February 2020.
14. 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 October 27, 2020. Accessed on January 8, 2021.