Ophthalmic Antihistamine Step Therapy Program Summary

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace and KeyRx.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

FDA APPROVED INDICATIONS AND DOSAGE[1-4]

Agent(s)	Indication(s)
Alocril® (nedocromil sodium) Ophthalmic solution	Treatment of itching associated with allergic conjunctivitis
Bepreve® (bepotastine besilate)[a] Ophthalmic solution	Treatment of itching associated with signs and symptoms of allergic conjunctivitis
Lastacaft® (alcaftadine) Ophthalmic solution	Prevention of itching associated with allergic conjunctivitis
Zerviate™ (cetirizine) Ophthalmic solution	Treatment of ocular itching associated with allergic conjunctivitis

a– generic available

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

American Academy of Ophthalmology suggests mild allergic conjunctivitis can be treated with over-the-counter (OTC) antihistamine/vasoconstrictor agents or with a more effective second-generation topical histamine H1-receptor antagonist. If the condition is frequently recurrent or persistent, mast cell stabilizers may be used to maintain comfort. Ophthalmic allergy preparations with dual antihistamine and mast-cell stabilizing properties may be used for either acute or chronic disease.[5] Topical dual activity agents are generally clinically superior due to both symptom/sign relief and tolerability. These agents are considered first-line treatment and provide the benefits of immediate relief from antihistamines along with the prophylactic benefit of mast cell stabilizers. Randomized control trials comparing dual activity agents (e.g., olopatadine to ketotifen, olopatadine to bepotastine) have found conflicting information regarding efficacy between products. Some have found patient preference and improvement in itching, while others have shown no difference in efficacy.[6] The American Academy of Ophthalmology does not indicate an agent preference.[5]

Safety[1-4]
*Alocril*is contraindicated in patients who have shown hypersensitivity to nedocromil or to any of the other ingredients

Bepreve is contraindicated in patients with a history of hypersensitivity reactions to bepotastine or any of the other ingredients.

Lastacaft is contraindicated in patients with hypersensitivity to any component in the product.

Zerviate has no FDA labeled contraindications for use.

REFERENCES

1. Alocril prescribing information. Allergan, Inc. June 2018.
2. Bepreve prescribing information. ISTA Pharmaceuticals, Inc. August 2022.
3. Lastacaft prescribing information. Allergan, Inc. December 2021.
4. Zerviate prescribing information. Eyevance Pharmaceuticals, LLC. February 2020.
5. Dupuis, P., Prokopich, C. L., Hynes, A.*, Kim, H. (2020)* A contemporary look at allergic conjunctivitis. *Allergy Asthma & Clinical Immunology,* 16 https://doi.org/10.1186/s13223-020-0403-9

Ophthalmic Antihistamine Step Therapy

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Alocril® (nedocromil sodium) **Bepreve®** (bepotastine besilate)[a] **Lastacaft®** (alcaftadine) **Zerviate™** (cetirizine)	All generic ophthalmic antihistamines

a- Generic available

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Target Agents will be approved when ONE of the following is met:

1. The patient has a medication history of use with ONE prerequisite agent
   OR
2. BOTH of the following:
   A. The prescriber has stated that the patient has tried a generic ophthalmic antihistamine agent
      AND
   B. The generic ophthalmic antihistamine agent was discontinued due to lack of effectiveness or an adverse event
   OR
3. The patient has an intolerance or hypersensitivity to ONE prerequisite antihistamine agent
   OR
4. The patient has an FDA labeled contraindication to ALL prerequisite agents
   OR
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   OR
6. The prescriber has provided documentation that ALL prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

 Effective: 09/01/2023