MEDICAL MUTUAL®

Drug Policy

Policy:	Ophthalmic Antihistamine Preferred Step Therapy	Annual Review Date: 04/18/2024
Impacted Drugs:	• loteprednol etabonate 0.2% ophthalmic suspension – generic • Zerviate™ (cetirizine 0.24% ophthalmic solution – Eyevance)	Last Revised Date: 04/18/2024

OVERVIEW

All of the ophthalmic anti-allergic agents are generally indicated for the treatment of allergic conjunctivitis. Conjunctivitis is inflammation of the outer lining of the eye, known as the conjunctiva. Conjunctivitis may be infectious or non-infectious; common types of non-infectious conjunctivitis include allergic, mechanical/irritative/toxic, and neoplastic. Allergic conjunctivitis affects an estimated 40% of the population.

POLICY STATEMENT

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

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are 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: generic loteprednol etabonate 0.2% ophthalmic suspension, Zerviate

CRITERIA

1. If the patient has tried one Step 1 product, authorization for a Step 2 product may be given.

2. If the patient requires the concurrent use of generic loteprednol etabonate 0.2% ophthalmic suspension and an H_1 antagonist or an H_1 antagonist/mast cell stabilizer, approve generic loteprednol etabonate 0.2% ophthalmic suspension. Note: An example of an H_1 antagonist is Zerviate. Examples of H_1 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 generic loteprednol etabonate 0.2% ophthalmic suspension.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 day (1 year)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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3. Azelastine solution [prescribing information]. Lake Forest, IL: Akorn, Inc.; November 2017.
4. Elestat® solution [prescribing information]. Irvine, CA: Allergan, Inc.; January 2012.
5. Pataday™ [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; February 2017.
6. Bepreve® solution [prescribing information]. Bridgewater, NJ: Bausch & Lomb, a division of Valeant Pharmaceuticals North America LLC; February 2018.
7. Lastacaft® solution [prescribing information]. Irvine, CA: Allergan, Inc.; February 2016.
8. Emadine® solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc.; October 2018.
9. Alrex® suspension [prescribing information]. Bridgewater, NJ: Bausch & Lomb, a division of Valeant Pharmaceuticals North America LLC; May 2016.
10. Zaditor® Drug Facts. Fort Worth, TX: Alcon Laboratories, Inc.; October 2018.
11. Alaway® Drug Facts. Tampa, FL: Bausch & Lomb Pharmaceuticals, Inc.; August 2015.
12. Pazeo® solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc; April 2017.
13. Zerviate solution [prescribing information]. Lake Forest, IL: Akorn Inc; May 2017.
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 December 10, 2021. Accessed on October 13, 2021.