Clinical Policy: Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers

Reference Number: OH.PHAR.PPA.75
Effective Date: 01/01/2020 Revision Log
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

OPHTHALMIC AGENTS: MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CROMOLYN (generic of Crolom®)	ALOCRIL® (nedocromil) ALOMIDE® (lodoxamide)

OPHTHALMIC AGENTS: ANTIHISTAMINE/MAST CELL STABILIZERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AZELASTINE (generic of Optivar®) KETOTIFEN (generic of Alaway®, Zaditor®) OLOPATADINE (generic of Patanol®)	BEPREVE® (bepotastine) EPINASTINE (generic of Elestat®) LASTACAFT® (alcaftadine)

FDA approved indication(s)

Alocril is indicated for:

- Treatment of itching related to allergic ocular disorders such as allergic conjunctivitis in adults and children who are older than 3 years of age.

Alomide is indicated for:

- Treatment of ocular inflammatory states such as vernal conjunctivitis, vernal keratitis, or vernal keratoconjunctivitis in adults and children 2 years of age and older.

Azelastine is indicated for:

- Treatment of ocular pruritus associated with allergic conjunctivitis in adults and children 3 years of age and older.

Bepreve is indicated for:

- Treatment of itching (ocular pruritus) associated with signs and symptoms of allergic conjunctivitis in adults and children 2 years of age and older.

Cromolyn is indicated for:

- Treatment of allergic ocular disorders such as allergic conjunctivitis, allergic keratoconjunctivitis, giant papillary conjunctivitis (GPC), vernal keratitis, and vernal keratoconjunctivitis in adults and children who are older than 4 years of age.

Epinastine is indicated for:

- Prevention of ocular pruritus associated with allergic conjunctivitis for adults and children 2 years of age and older.

Ketotifen is indicated for:

- Temporary prevention of ocular pruritus due to allergic conjunctivitis for adults and children 3 years of age and older.

Lastacaft is indicated for:

- Prevention of ocular pruritus associated with allergic conjunctivitis for adults and children 2 years of age and older.

Olopatadine is indicated for:

- Treatment of the signs and symptoms of allergic conjunctivitis, including ocular pruritus for adults and children 2 years of age and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of ≥ 14 days of one preferred medication, unless member meets one of the following (a, b, or c):
    a. Allergy to medications not requiring prior approval;
    b. Contraindication to or drug interaction with medications not requiring prior approval;
    c. History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
GPC: Giant Papillary Conjunctivitis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business

and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cromolyn (Crolom®)	1 to 2 drops (1.6 mg per drop) in each eye 4 to 6 times per day at regular intervals	N/A
Azelastine (Optivar®)	1 drop in each affected eye BID	N/A
Ketotifen (Alaway®, Zaditor®)	1 drop in the affected eye(s) every 8-12 hours	3 drops/day in each affected eye
Olopatadine (Pataday®, Patanol ®) Pazeo® (olopatadine)	Olopatadine (Pataday®): 1 drop in each affected eye BID at an interval of 6 to 8 hours Olopatadine (Patanol®): 1 drop in each affected eye QD Pazeo® (olopatadine): 1 drop in each affected eye QD	Olopatadine (Pataday®): 2 drops/day in each affected eye Olopatadine (Patanol®): 1 drop/day in each affected eye Pazeo®(olopatadine): 1 drop/day in each affected eye

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed warnings

- Contraindications(s): none reported
- Boxed warning(s): none reported

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Alocril	1 to 2 drops in each eye BID at regular intervals	N/A
Alomide	1 to 2 drops in affected eye(s) QID; not to be used longer than 3 months	8 drops/day per affected eye
Bepreve	1 drop in affected eye(s) BID	2 drops/day per affected eye
Epinastine	1 drop in affected eye(s) BID; continue treatment through period of allergen exposure, even when symptoms are absent	2 drops/day per affected eye
Lastacaft	1 drop in each eye QD; duration of treatment has not been defined by the manufacturer; however, the safety of administering over a 6-week period was evaluated in a clinical study	1 drop/day in each eye

For preferred agents please see Appendix B.

V. Product Availability

Drug	Availability
Alocril	Ophthalmic solution: 2%
Alomide	Ophthalmic solution: 0.1%
Bepreve	Ophthalmic solution: 1.5%
Epinastine	Ophthalmic solution: 0.05%
Lastacaft	Ophthalmic solution: 0.25%

VI. References
Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.