Clinical Policy: Anti-Allergy Ophthalmics
Reference Number: CP.PST.03
Effective Date: 02/13
Last Review Date: 08/17 Revision Log
Line of Business: Medicaid

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

Description
The following are anti-allergy ophthalmics requiring step therapy: lodoxamide (Alomide®) and nedocromil (Alocril®).

FDA approved indication
Anti-allergy ophthalmics are indicated for the treatment of various allergic ocular disorders such as allergic conjunctivitis, vernal conjunctivitis, vernal keratitis, and vernal keratoconjunctivitis.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Alocril and Alomide are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. Electronic Step Therapy for Anti-Allergy Ophthalmics (must meet all)**:**
1. Previous use of at least two of the following: ketotifen 0.025% ophthalmic solution, naphazoline with pheniramine ophthalmic solution, azelastine ophthalmic solution, or cromolyn 4% ophthalmic solution, unless contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed 8 drops/eye/day.

Approval duration: 12 months

II. Continued Therapy
A. Electronic Step Therapy for Anti-Allergy Ophthalmics (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed 8 drops/eye/day.

Approval duration: 12 months

III. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose

Alocril	1-2 drops in each eye twice daily at regular intervals.	8 drops/day/eye
Alomide	1-2 drops in affected eye(s) four times per day; should not be used for longer than 3 months.	8 drops/day/affected eye

V. Product Availability

Drug	Availability
Alocril	2% ophthalmic drops, solution: 5 mL
Alomide	0.1% ophthalmic drops, solution: 10 mL

VI. Workflow Document

N/A

VII. References

1. Lodoxamide (Alomide®) Drug monograph. Clinical Pharmacology. Accessed April 4, 2017.
2. Nedocromil (Alocril®) Drug monograph. Clinical Pharmacology. Accessed April 4, 2017.
3. Azelastine (Optivar®) Drug monograph. Clinical Pharmacology. Accessed November 19, 2015.
4. Alcaftadine (Lastacaft®) Drug monograph. Clinical Pharmacology. Accessed November 19, 2015
5. Olopatadine (Pataday®, Patanol®) Drug monograph. Clinical Pharmacology. Accessed November 19. 2015
6. Bepotastine (Bepreve®) Drug monograph. Clinical Pharmacology. Accessed November 19, 2015
7. Epinastine (Elestat®) Drug monograph. Clinical Pharmacology. Accessed November 19. 2015.
8. Emedastine (Emadine®) Drug monograph. Clinical Pharmacology. Accessed November 19, 2015.
9. American Optometric Association. Optometric clinical practice guideline: care of the patient with conjunctivitis. St. Louis, MO. November 2002. Available at http://www.aoa.org/optometrists/tools-and-resources/clinical-care-publications/clinical-practice-guidelines?sso=y. Accessed April 2017.
10. Bielory L. Ocular allergy guidelines: a practical treatment algorithm. Drugs. 2002; 62(11):1611-1634.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
References updated.	02/14	02/14
References updated.	02/15	02/15
Converted to new template; Requirement for diagnosis removed as these agents are on PDL with step therapy edit.	02/16	02/16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added that preferred medications must have been used in the last 12 months. Added renewal criteria. References updated.		
Removed 12 month failure duration from criteria; Additional references added.	02/16	05/16
Removed requirement of Optivar, it is PDL; added criteria not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit and azelastine to the trial/failure list.	07/16	08/16
Removed age restriction as those are not absolute contraindications per PI	04/17	08/17

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.