STEP THERAPY POLICY

POLICY: Ophthalmic Anti-Allergics – Mast Cell Stabilizers Step Therapy Policy
- Alocril® (nedocromil sodium 2% ophthalmic solution – Allergan)
- Alomide® (lodoxamide tromethamine 0.1% ophthalmic solution – Alcon/Novartis)
- Cromolyn sodium 4% ophthalmic solution (generic only)

REVIEW DATE: 02/14/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The ophthalmic mast cell stabilizers are indicated for the treatment of **allergic conjunctivitis**.[1-3] Cromolyn sodium 4% ophthalmic solution and Alomide are specifically indicated for the treatment of vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis. Alomide is dosed four times daily; Alocril is dosed twice daily; and cromolyn sodium 4% ophthalmic solution is dosed four to six times daily at regular intervals.

Guidelines

The Conjunctivitis Preferred Practice Pattern® (2018) and Cornea/External Disease Summary Benchmarks (2022) from the American Academy of Ophthalmology state that mast cell stabilizers can be used if the patient's conjunctivitis is frequently recurrent or persistent despite treatment with a topical antihistamine/vasoconstrictor or topical histamine (H1)-receptor antagonist.[4,5] The Panel does not note a preference for one mast cell stabilizer over another.

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.

Ophthalmic Anti-Allergics – Mast Cell Stabilizers product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

Step 1: generic cromolyn sodium ophthalmic solution

Step 2: Alocril, Alomide

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Alomide® ophthalmic solution [prescribing information]. Fort Worth, TX: Alcon; July 2022.
2. Alocril® ophthalmic solution [prescribing information]. Irvine, CA: Allergan; July 2018.
3. Cromolyn sodium ophthalmic solution [prescribing information]. Princeton, NJ: Sandoz; August 2021.
4. 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.
5. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel, Hoskins Center for Quality Eye Care. Summary benchmarks for preferred practice patter guidelines. Available at: https://www.aao.org/summary-benchmark-detail/cornea-external-disease-summary-benchmarks-2020. Updated December 2022. Accessed on January 29, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/25/2023
Annual Revision	No criteria changes	02/14/2024