



STEP THERAPY POLICY

- POLICY:** Ophthalmic Corticosteroids Step Therapy Policy
- Clobetasol propionate 0.05% ophthalmic suspension – Formosa (branded product)
 - Dexamethasone sodium phosphate ophthalmic solution 0.1% (generic only)
 - Durezol® (difluprednate ophthalmic emulsion 0.05% – Novartis, generic)
 - Flarex® (fluorometholone acetate ophthalmic suspension 0.1% – Eyevance)
 - Fluorometholone ophthalmic suspension 0.1% (generic only)
 - FML® Forte (fluorometholone ophthalmic suspension 0.25% – Allergan)
 - FML® Liquifilm (fluorometholone ophthalmic suspension 0.1% – Allergan, generic)
 - Inveltys™ (loteprednol etabonate ophthalmic suspension 1% – Kala)
 - Lotemax® (loteprednol etabonate ophthalmic gel 0.5% [generic], ophthalmic suspension 0.5% [generic], ophthalmic ointment 0.5% – Bausch + Lomb)
 - Lotemax® SM (loteprednol etabonate ophthalmic gel 0.38% – Bausch + Lomb)
 - Maxidex® (dexamethasone ophthalmic suspension 0.1% – Novartis)
 - Pred Mild® (prednisolone acetate ophthalmic suspension 0.12% – Allergan)
 - Prednisolone acetate ophthalmic suspension 1% (generic only)

REVIEW DATE: 10/09/2024

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 corticosteroid products are (generally) indicated for treatment of a variety of **conditions, including anterior uveitis; corneal injury; inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe; postoperative inflammation and/or pain following ocular injury; and seasonal allergic conjunctivitis.**¹ Some of the products are also indicated for the treatment of **post-operative inflammation and/or pain following ocular surgery.** Durezol is also indicated for the treatment of **endogenous anterior uveitis.**² Two clinical studies demonstrated Durezol to be equally effective as prednisolone acetate ophthalmic suspension 1% in treating patients with endogenous anterior uveitis.

Clinical studies that directly compare all of the currently available ophthalmic corticosteroid products have not been performed. It is generally recognized that all ophthalmic corticosteroids are effective agents for treating a variety of ocular inflammatory conditions.³

Many of the ophthalmic corticosteroid products are preserved with benzalkonium chloride.¹ The following products included in this policy are not preserved with benzalkonium chloride: Durezol (sorbic acid) and Lotemax ophthalmic ointment (prescribing information does not note a preservative).^{2,4}

POLICY STATEMENT

This program has been developed to encourage the use of two Step 1 Products 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.

Step 1: generic dexamethasone sodium phosphate ophthalmic solution 0.1%, generic difluprednate ophthalmic emulsion 0.05%, generic fluorometholone ophthalmic suspension 0.1%, generic loteprednol etabonate ophthalmic suspension 0.5%, generic prednisolone acetate ophthalmic suspension 1%

Step 2: Clobetasol propionate 0.05% ophthalmic suspension, Durezol, Flarex, FML Forte, FML Liquifilm, Inveltys, Lotemax ophthalmic ointment 0.5%, Lotemax ophthalmic gel 0.5%, Lotemax SM, Maxidex, Pred Mild

Ophthalmic Corticosteroids Step Therapy Policy 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.

CRITERIA

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

2. If the patient has an allergy to benzalkonium chloride, approve Durezol or Lotemax ophthalmic ointment.

REFERENCES

1. Facts and Comparisons Online. Wolters Kluwer Health, Inc.; 2024. Available at <https://fco.factsandcomparisons.com/lco/action/home>. Accessed on October 04, 2024. Search terms: ophthalmic corticosteroids.
2. Durezol® [prescribing information]. East Hanover, NJ: Novartis; November 2020.
3. Fung AT, Tran T, Lim LL, et al. Local delivery of corticosteroids in clinical ophthalmology: A review. *Clin Exp Ophthalmol*. 2020;48(3):366-401.
4. Lotemax® ophthalmic ointment [prescribing information]. Bridgewater, NJ: Bausch Health; November 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Durezol: Added Durezol to the exception criterion for a patient with an allergy to benzalkonium chloride. FML SOP: Removed from Step 2 (obsolete).	09/20/2023
Annual Revision	Clobetasol propionate 0.05% ophthalmic suspension: Added to Step 2.	10/09/2024

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