

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

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.

Automation: A patient with a history of two Step 1 Products within the 130-day look-back period is excluded from Step Therapy.

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

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.
3. No other exceptions are recommended.

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