

STEP THERAPY POLICY

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

REVIEW DATE: 09/22/2021; selected revision 10/13/2021

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

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), FML SOP (phenylmercuric acid), and Lotemax ophthalmic ointment (prescribing information does not note a preservative).^{2,4,5}

Intraocular Pressure

The American Academy of Ophthalmology (AAO) Preferred Practice Patterns (PPPs) for blepharitis and conjunctivitis (both from 2018) note that corticosteroids with poor ocular penetration (e.g., fluorometholone) or site-specific steroids (e.g., rimexolone, loteprednol), may be less likely to result in elevated intraocular pressure (IOP) or cataract formation.^{6,7} If corticosteroids are used in chronic or recurrent conjunctivitis, baseline and periodic measurement of IOP and pupillary dilation should be performed to monitor for cataract and glaucoma. All patients using ophthalmic corticosteroids for ≥ 10 days should have their IOP monitored.¹ The AAO PPP for cataract in the adult eye (2016) notes that topical corticosteroid use can cause elevated IOP in eyes that are “steroid responders”.⁸ Steroid responders are individuals with disproportionate increases in IOP in response to a small dose of corticosteroid or a short

duration of treatment.⁹ IOP monitoring should be performed in all patients being treated with postoperative corticosteroids. Discontinuation of corticosteroid therapy results in a reduction of the IOP to normal levels.

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.

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 fluorometholone ophthalmic suspension 0.1%, generic loteprednol etabonate ophthalmic suspension 0.5%, generic prednisolone acetate ophthalmic suspension 1%

Step 2: Durezol (brand and generic), Flarex, FML Forte, FML Liquifilm, FML SOP, 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 is diagnosed with endogenous anterior uveitis, approve Durezol (brand or generic).
3. If the patient has an allergy to benzalkonium chloride, approve Durezol (brand or generic), FML SOP ointment, or Lotemax ophthalmic ointment.
4. No other exceptions are recommended.

REFERENCES

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3. Corticosteroids. Topical corticosteroids remain the cornerstone of ocular anti-inflammatory therapy. *Review of Optometry*. 2002; May 15.
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5. Lotemax ophthalmic ointment [prescribing information]. Bridgewater, NJ: Bausch Health; December 2020.
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