Clinical Policy: Ophthalmic Corticosteroids

Reference Number: HIM.PA.03
Effective Date: 01.01.20
Last Review Date: 11.24
Line of Business: HIM

Revision Log

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

Description

The following are ophthalmic corticosteroids requiring prior authorization: dexamethasone (Maxidex®), difluprednate (Durezol®), fluorometholone (FML®, FML® Forte), loteprednol (Alrex®, Lotemax®), and prednisolone (Pred Mild®).

FDA Approved Indication(s)

Alrex is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis.

Durezol is indicated for the treatment of:

- Inflammation and pain associated with ocular surgery
- Endogenous anterior uveitis

FML and FML Forte are indicated for the treatment of corticosteroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

Lotemax suspension is indicated for the treatment of:

- Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.
- Post-operative inflammation following ocular surgery

Lotemax gel and ointment are indicated for the treatment of post-operative inflammation and pain following ocular surgery.

Maxidex is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

Pred Mild is indicated for the treatment of mild to moderate noninfectious allergic and inflammatory disorders of the lid, conjunctiva, cornea, and sclera (including chemical and thermal burns).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Alrex, Durezol, FML, FML Forte, Lotemax, Maxidex, and Pred Mild are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All FDA-Approved Indications (must meet all)**:**

1. Request is for one of the following uses (a – d):
   a. Durezol, Lotemax: following ocular surgery;
   b. FML, FML Forte, Lotemax suspension, Maxidex, Pred Mild: inflammation of the eye;
   c. Alrex: seasonal allergic conjunctivitis;
   d. Durezol: uveitis;
2. If request is for FML or FML Forte: Age ≥ 2 years;
3. If request is for Alrex or Lotemax: Age ≥ 18 years;
4. Failure of at least two preferred generic ophthalmic corticosteroids (e.g., dexamethasone, fluorometholone, prednisolone) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. If request is for the brand name drug with the same active ingredient as previously trialed, medical justification why the requested brand name drug will work despite inadequate response to the generic (e.g., contraindications to excipients);
6. Request does not exceed one of the following (a, b, c, d, or e):
   a. Alrex, FML, FML Forte, Lotemax suspension, Pred Mild: 1 bottle per 30 days;
   b. Durezol: 2 bottles per 30 days;
   c. Lotemax ointment: 2 tubes per 30 days;
   d. Lotemax gel: 3 bottles per 30 days;
   e. Maxidex: 4 bottles per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (health insurance marketplace), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (health insurance marketplace), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. All FDA-Approved Indications (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, request does not exceed one of the following (a, b, c, d, or e):
   a. Alrex, FML, FML Forte, Lotemax suspension, Pred Mild: 1 bottle per 30 days;
   b. Durezol: 2 bottles per 30 days;
   c. Lotemax ointment: 2 tubes per 30 days;
   d. Lotemax gel: 3 bottles per 30 days;
   e. Maxidex: 4 bottles per 30 days.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (health insurance marketplace), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (health insurance marketplace), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dexamethasone 0.1% solution	1 to 2 drops in affected eye four to six times per day.	12 drops/day in affected eye
fluorometholone 0.1% suspension (FML Liquifilm)	1 drop in affected eye BID to QID.	4 drops/day in affected eye
prednisolone 1% solution/suspension (Omnipred®, Pred Forte®, Pred Mild)	1 drop in affected eye BID to QID.	4 drops/day in affected eye

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures
  - Pred Mild: acute untreated purulent ocular infections
  - Alrex, FML, FML Forte, Lotemax, Maxidex, and Pred Mild: hypersensitivity
  - Maxidex: acute, untreated bacterial infections
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
dexamethasone (Maxidex)	Steroid responsive inflammatory conditions	1 to 2 drops in affected eye. In severe disease, drops may be used hourly, being tapered to discontinuation as the inflammation subsides. In mild disease, drops may be used up to four to six times daily.	12 drops/day in affected eye; 4 bottles/30 days
difluprednate (Durezol)	Ocular surgery	1 drop in affected eye QID beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by BID dosing for 1 week and then tapered based on response.	4 drops/day in affected eye; 2 bottles/30 days

Drug Name	Indication	Dosing Regimen	Maximum Dose
	Endogenous anterior uveitis	1 drop in affected eye QID for 14 days followed by tapering as clinically indicated.	4 drops/day in affected eye; 2 bottles/30 days
fluorometholone suspension (FML, FML Forte)	Steroid responsive inflammatory conditions	1 drop in affected eye BID to QID. During the initial 24 to 48 hours, the dosing frequency may be increased to one application every four hours.	4 drops/day in affected eye; 1 bottle/30 days
loteprednol (Alrex)	Seasonal allergic conjunctivitis	1 drop in the affected eye QID	4 drops/day in affected eye; 1 bottle/30 days
loteprednol (Lotemax)	Steroid responsive disease	Suspension: 1 to 2 drops in the affected eye QID. During the initial treatment within the first week, dosing may be increased up to 1 drop every hour if necessary.	Suspension: 8 drops/day in affected eye; 1 bottle (suspension)
	Ocular surgery	Begin treatment 24 hours after surgery for 2 weeks Suspension/0.5% gel: 1 to 2 drops in the affected eye QID. Ointment: Approximately ½ inch ribbon of ointment in affected eye QID.	Suspension/0.5% gel: 8 drops/day in affected eye; 1 bottle (suspension) or 3 bottles (gel)/30 days Ointment: 2 inch ribbon/day in affected eye; 2 tubes/30 days
prednisolone (Pred Mild)	Steroid responsive inflammatory conditions	1 drop in affected eye BID to QID. During the initial 24 to 48 hours, the dosing frequency may be increased to one application every four hours.	4 drops/day in affected eye; 1 bottle/30 days

VI. Product Availability

Drug Name	Availability
dexamethasone (Maxidex)	Multidose bottle with 0.1% suspension: 5 mL
difluprednate (Durezol)	Multidose bottle with 0.05% suspension: 5 mL
fluorometholone suspension (FML, FML Forte)	Multidose bottle with 0.25% suspension: 5 mL, 10 mL
loteprednol (Alrex)	Multidose bottle with 0.2% suspension: 5 mL in 7.5 mL bottle, 10 mL in 10 mL bottle
loteprednol (Lotemax)	Multidose bottle with 0.5% suspension: 5 mL, 10 mL, 15 mL

Drug Name	Availability
	Multidose bottle with 0.5% gel: 5 g in 10 mL bottle Tube with 0.5% ointment: 3.5 g
prednisolone (Pred Mild)	Multidose bottle with 0.12% suspension: 5 mL, 10 mL

VII. References

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10. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 19, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2020 annual review: no significant changes; removed loteprednol from list of preferred generic ophthalmic corticosteroids as this product requires PA; references reviewed and updated.	07.22.20	11.20
4Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	06.28.21	11.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.18.22	11.22
4Q 2023 annual review: for Lotemax, updated FDA approved indication section with applicable indications for gel, suspension, and ointment per respective prescriber information; updated initial approval criteria from "Lotemax: inflammation of the eye" to "Lotemax suspension: inflammation of the eye"; updated section V to align Lotemax dosing with respective formulation and removed FML ointment; removed "fluorometholone ointment" from section VI as it is discontinued; references reviewed and updated.	08.01.23	11.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.22.24	11.24

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.