Clinical Policy: Ophthalmic Agents: Ophthalmic Steroids

Reference Number: OH.PHAR.PPA.100
Effective Date: 01/01/2021 Revision Log
Last Review Date: 11.20
Line of Business: Medicaid

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

Description

Ophthalmic Agents: Ophthalmic Steroids

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DEXAMETHASONE SODIUM PHOSPHATE DUREZOL® (difluprednate) FLUOROMETHOLONE FML FORTE® (fluorometholone) FML S.O.P. ® (fluorometholone) PRED MILD® (prednisolone acetate) PREDNISOLONE ACETATE PREDNISOLONE SODIUM PHOSPHATE	ALREX® (loteprednol etabonate) FLAREX® (fluorometholone acetate) INVELTYS® (loteprednol etabonate) LOTEMAX® (loteprednol etabonate) LOTEMAX® SM (loteprednol etabonate) LOTEPREDNOL MAXIDEX® (dexamethasone sodium phosphate)

FDA approved indication(s)

Alrex is indicated for:

- Temporary relief of the signs and symptoms of seasonal allergic conjunctivitis

Durezol is indicated for:

- Treatment of postoperative ocular pain and postoperative ocular inflammation
- Treatment of endogenous anterior uveitis

Flarex, fluorometholone, FML Forte, and FML S.O.P are indicated for:

- Treatment of corticosteroid-responsive ophthalmic disorders including allergic conjunctivitis, ocular burns or trauma due to corneal injury resulting from chemical, thermal or penetration trauma, giant papillary conjunctivitis (GPC), keratitis, postoperative ocular inflammation, vernal keratoconjunctivitis, and chronic anterior uveitis

Inveltys is indicated for:

- Treatment of postoperative ocular inflammation following ocular surgery
- Treatment of postoperative ocular pain following ocular surgery

Lotemax (loteprednol) is indicated for:

- Treatment of steroid responsive ophthalmic diseases including acute allergic conjunctivitis, acne rosacea, giant papillary conjunctivitis (GPC), iritis, keratitis, and cyclitis
- Use as an alternative corticosteroid for the treatment of uveitis
- Treatment of postoperative ocular inflammation following ocular surgery
- Treatment of postoperative ocular pain following ocular surgery

Limitation of use: Lotemax should not be used in patients who require a more potent corticosteroid for uveitis. Lotemax is less effective than prednisolone 1% in the treatment of acute anterior uveitis.

Lotemax SM is indicated for:

- Treatment of postoperative ocular inflammation following ocular surgery
- Treatment of postoperative ocular pain following ocular surgery

Maxidex (dexamethasone sodium phosphate) is indicated for:

- Treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment inflammation of the globe, such as allergic conjunctivitis, eyelid acne rosacea, superficial punctate keratitis, herpes zoster ocular infection associated keratitis, iritis, cyclitis, vernal keratoconjunctivitis, selected infective viral conjunctivitis or postoperative ocular inflammation when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal abrasion, corneal ulcer, or corneal injury from chemical or thermal burns, or penetration of foreign bodies; systemic treatment may be indicated for uveitis, sympathetic ophthalmia, and ocular inflammatory conditions unresponsive to topical corticosteroids

Pred Mild (prednisolone acetate) and prednisolone sodium phosphate are indicated for:

- Treatment of corticosteroid-responsive ophthalmic disorders including allergic conjunctivitis, allergic marginal corneal ulcer, anterior segment inflammation, bacterial conjunctivitis, chorioretinitis, choroiditis, cyclitis, endophthalmitis†, Graves' ophthalmopathy, herpes zoster ocular infection (herpes zoster ophthalmicus) with appropriate antiviral therapy, iritis, non-specific keratitis or superficial punctate keratitis, postoperative ocular inflammation, optic neuritis, diffuse posterior uveitis, vernal keratoconjunctivitis, or for corneal injury from chemical, radiation, or thermal burns or penetration of foreign bodies

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 Buckeye Health Plan, an affiliate of Centene Corporation® that Ophthalmic Steroids are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of at least two preferred medications, each used for ≥ 14 days, unless member meets one of the following (a, b, or c):
    a) Allergy to medications not requiring prior approval;
    b) Contraindication to or drug interaction with medications not requiring prior approval;

c) History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 30 days

II. 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 – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration
FML: Fluorometholone
GPC: giant papillary conjunctivitis

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Dexamethasone sodium phosphate	Adults, Adolescents, and Children: Instill 1 or 2 drops of 0.1% ophthalmic solution in the affected eye(s) every hour during the day and every 2 hours at night; reduce application to every 4 hours (while awake) once a favorable response occurs. Later, further reduction in dosage to 1 drop 3 or 4 times daily may suffice to control symptoms.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of dexamethasone treatment, and on patient response.
Durezol® (difluprednate)	**Postoperative ocular pain and postoperative ocular inflammation:** *Adults:* Instill 1 drop into the conjunctival sac of the affected eye(s) 4 times daily beginning 24	4 drops/day in each affected eye

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	hours after surgery; continue giving 4 times/day for the first 2 weeks of the postoperative period, then administer 2 times daily for 1 week. At the end of the third week, taper dose based on response. *Infants, Children, and Adolescents:* Instill 1 drop into the conjunctival sac of the affected eye(s) 4 times daily beginning 24 hours after surgery; continue giving 4 times/day for the first 2 weeks of the postoperative period, then administer 2 times daily for 1 week. At the end of the third week, taper dose based on response. **Endogenous anterior uveitis:** *Adults:* Instill 1 drop into the conjunctival sac of the affected eye(s) 4 times daily for 14 days followed by tapering as clinically indicated.	
Fluorometholone, FML Forte®, and FML S.O.P®	Fluorometholone and FML Forte®: Adults, Adolescents and Children >= 2 years: 1 drop into the conjunctival sac 2—4 times per day. During the initial 24—48 hours, may apply 1 drop every 4 hours. If no improvement after 2 days, re-evaluate. FML S.O.P®: Adults, Adolescents and Children >= 2 years: Approximately ½ of an inch applied to the conjunctival sac	Corticosteroid dosage must be individualized and is highly variable depending on the nature and severity of the disease and on patient response. Renewal of fluorometholone prescriptions beyond 20 ml of ophthalmic suspension or 8 grams of ophthalmic ointment should be made by only

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	1—3 times per day. During the initial 24—48 hours, may apply every 4 hours. If no improvement after 2 days, re-evaluate.	after re-examination with the aid of magnification.
Pred Mild®(prednisolone acetate)	*Adults:* 1 to 2 drops in the affected eye(s) 2 to 4 times daily or 2 drops in the affected eye(s) 4 times per day. During the initial 24 to 48 hours, may increase dose frequency if necessary. If signs and symptoms fail to improve after 2 days, re-evaluate. Once the condition is responding, lower dosage may be used, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, and on patient response.
Prednisolone sodium phosphate	Adults: 1 or 2 drops into affected eye(s) every hour while awake, and every 2 hours at night. When a favorable response is observed, reduce dosage to 1 drop every 4 hours. Thereafter, 1 drop given 3 to 4 times daily may suffice to control symptoms. The dosage and duration of treatment will vary with the condition treated and may extend from a few days to several weeks, according to therapeutic response. Relapses, more common in chronic active lesions than in self-limited conditions, usually respond to retreatment. In chronic conditions, withdrawal of treatment should be carried out by	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, and on patient response.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	gradually decreasing the frequency of applications.	

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Loteprednol: herpes simplex keratitis (dendritic keratitis), ocular infection
  - Fluorometholone: fungal infection, herpes simplex keratitis (dendritic keratitis), mycobacterial infection, varicella, viral infection
  - Dexamethasone: fungal infection, glaucoma, herpes simplex keratitis (dendritic keratitis), ocular infection, rupture of posterior ocular lens capsule, tympanic membrane perforation
  - Durezol: corticosteroid hypersensitivity, fungal infection, glycerin hypersensitivity, herpes simplex keratitis (dendritic keratitis), mycobacterial infection, polysorbate 80 hypersensitivity, varicella, viral infection
  - Prednisolone: fungal infection, herpes simplex keratitis (dendritic keratitis), varicella, viral infection
- Boxed warning(s): none reported

IV. Dosage and Administration

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Alrex® (loteprednol)	Adults: Apply 1 drop into the conjunctival sac of the affected eye(s) 4 times daily	4 drops/day in each affected eye
Flarex® (fluorometholone)	Adults, Adolescents and Children >= 2 years: 1 drop into the conjunctival sac 2—4 times per day. During the initial 24—48 hours, may apply 1 drop every 4	Corticosteroid dosage must be individualized and is highly variable depending on the nature and severity of the disease

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	hours. If no improvement after 2 days, re-evaluate	and on patient response. Renewal of fluorometholone prescriptions beyond 20 ml of ophthalmic suspension should be made by only after re-examination with the aid of magnification.
Inveltys® (loteprednol)	Adults: Apply 1 to 2 drops into the affected eye(s) twice daily, beginning the day after surgery and continuing for 2 weeks after surgery	4 drops/day in each affected eye
Lotemax® (loteprednol)	**Ophthalmic diseases and uveitis:** *Adults:* Apply 1 to 2 drops into the conjunctival sac of the affected eye(s) 4 times daily. During the first week, increase up to 1 drop every hour if needed. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated **Post ocular surgery:** *Suspension:* Adults*:* Apply 1 to 2 drops into the conjunctival sac of the affected eye(s) 4 times daily, beginning 24 hours after surgery and continuing for 2 weeks after surgery. *Ointment:* Apply a small amount (approximately one-half inch ribbon) into the conjunctival sac(s) 4 times daily, beginning 24 hours after surgery and continuing 2 weeks after surgery.	24 drops/day in each affected eye

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Lotemax SM®	Adults: Apply 1 drop into the conjunctival sac of the affected eye(s) 3 times daily, beginning 24 hours after surgery and continuing for 2 weeks after surgery.	3 drops/day in each affected eye
Maxidex® (dexamethasone sodium phosphate)	Adults, Adolescents, and Children: Instill 1 or 2 drops of 0.1% ophthalmic suspension in the affected eye(s). 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 4 to 6 times daily.	Dosage must be individualized and is highly variable depending on the nature and severity of the disease, route of dexamethasone treatment, and on patient response.

For preferred agents please see Appendix B.

V. Product Availability

Drug	Availability
Alrex® (loteprednol)	0.2% ophthalmic suspension
Dexamethasone sodium phosphate	0.1% ophthalmic solution
Durezol® (difluprednate)	0.05% ophthalmic emulsion
Flarex® (fluorometholone)	0.1% ophthalmic suspension
FML Forte®(fluorometholone)	0.25% ophthalmic suspension
FML S.O.P	0.1% ophthalmic ointment
Inveltys® (loteprednol)	1% ophthalmic suspension
Lotemax® (loteprednol)	0.5% ophthalmic suspension 0.5% ophthalmic gel 0.5% ophthalmic ointment
Lotemax SM® (loteprednol)	0.38% ophthalmic gel
Maxidex®	0.1% ophthalmic suspension
Pred Mild®	0.12% ophthalmic suspension
Prednisolone Acetate	1% ophthalmic suspension
Prednisolone sodium phosphate	1% ophthalmic solution

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	11/20	

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.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.