Clinical Policy: Loteprednol Etabonate (Eysuvis)

Reference Number: ERX.NPA.153
Effective Date: 03.01.21
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

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

Description
Loteprednol etabonate (Eysuvis™) is an ophthalmic corticosteroid.

FDA Approved Indication(s)
Eysuvis is indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Eysuvis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dry Eye Disease (must meet all)**:**

1. Diagnosis of dry eye disease;
2. Age ≥ 18 years;
3. Failure of artificial tears at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of at least one other ophthalmic anti-inflammatory agent (see *Appendix B* for examples) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed 1 bottle per 14 days.

Approval duration: 14 days

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Dry Eye Disease (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 bottle per month.

Approval duration: 14 days

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or one month (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
artificial tears (e.g., Visine dry eye relief)	1 to 2 drops in affected eye(s) BID or QID	various
ophthalmic anti-inflammatory agents for dry eye disease (e.g., loteprednol etabonate 0.2%, 0.5%) Note: Ophthalmic NSAIDs are not indicated.	1 to 2 drops in each eye BID to QID for up to 2 weeks	various

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): most viral disease 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
- Boxed warning(s): none reported

Appendix D: General Information

- Artificial tears are the standard therapy for all severity of dry eyes.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Dry eye disease	1-2 drops in each eye QID for up to two weeks	8 drops/day in each eye

VI. Product Availability

Ophthalmic suspension: 0.25% (10 mL bottle)

VII. References

1. Eysuvis Prescribing Information. Watertown, MA: Kala Pharmaceuticals, Inc.; October 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210933s000lbl.pdf. Accessed October 4, 2021.
2. American Academy of Ophthalmology Cornea/External Disease Committee. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. Chicago, IL: American Academy of Ophthalmology; November 2018. Available at: https://www.aaojournal.org/article/S0161-6420(18)32650-2/fulltext. Accessed October 4, 2021.
3. Aragona P, Giannaccare G, Mencucci R, et al. Modern approach to the treatment of dry eye, a complex multifactorial disease: a P.I.C.A.S.S.O. board review. British Journal of Ophthalmology 2021;105:446-453. http://dx.doi.org/10.1136/bjophthalmol-2019-315747

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.18.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	10.04.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.