

## **Clinical Policy: Loteprednol etabonate (Eysuvis)**

Reference Number: CP.PMN.260

Effective Date: 03.01.21

Last Review Date: 02.22

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Loteprednol etabonate (Eysuvis<sup>™</sup>) 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.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## **II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, request does not exceed 1 bottle per 14 days.

**Approval duration: 14 days**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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
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%)	1 to 2 drops in each eye BID to QID for up to 2 weeks	various
Note: Ophthalmic NSAIDs are not indicated.		

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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](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<sup>®</sup> 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](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; references to HIM.PHAR.21 revised to HIM.PA.154.	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. 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.

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**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.

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