# Pharmacy Policy Bulletin

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| **Title:** | Loteprednol etabonate (Eysuvis™) |
| **Policy #:** | Rx.01.245 |

***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for **Loteprednol etabonate (Eysuvis™)** as provided under the member's prescription drug benefit.

**Description:**

Dry eye disease (DED) is an ocular disease characterized by loss of homeostasis of the tear film resulting in ocular symptoms. This can lead to inflammation and damage of the ocular surface, tear film hyperosmolarity and neurosensory abnormalities. The prevalence of the disease is higher in women and increases with age, ranging from 5 to 50% in the United States. Some of the risk factors include hormonal changes, systemic diseases, nutritional deficiencies, and ophthalmic surgery.

Symptoms of chronic eye irritation with mild to moderate discomfort are commonly seen in dry eye disease. Some of the most common symptoms reported by patients include dryness, red eye, burning sensation, light sensitivity, and foreign body sensation. If severe, these can impact visual acuity and daily activities.

General treatment includes tear supplementation with artificial tears and environmental adjustments. Artificial tears are available in different formulations including drops, gels and ointments.

Loteprednol is an ophthalmic suspension corticosteroid indicated for short term use (up to 2 weeks) for relief of symptoms in dry eye disease.

**Policy:**

**INITIAL CRITERIA** Loteprednol etabonate (Eysuvis®) is approved when ALL of the following are met:

1. Diagnosis of dry eye disease; and
2. Prescribed by or in consultation with Ophthalmologist or Optometrist

Initial authorization: 14 days

**REAUTHORIZATION CRITERIA** Loteprednol etabonate (Eysuvis®) is reapproved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., improvement in dry eye symptoms); and
2. Prescribed by or in consultation with ophthalmologist or optometrist

Reauthorization: 14 days

**Black Box Warning as shown in the drug Prescribing Information:**

none

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Eysuvis™ (Loteprednol) [prescribing information]. Watertown, MA: Kala Pharmaceuticals, Inc. October 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210933s000lbl.pdf. Accessed on April 2, 2021.

Roni M. Shtein, MD. Dry eye disease In UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on April 2, 2021.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Brand Name | Generic Name |
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| Eysuvis™ | Loteprednol etabonate |

**Cross References:**

Rx.01.33 Off Label Use

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| **Policy Version Number:** | 1.0 |
| **P&T Approval Date:** | March 18, 2021 |
| **Policy Effective Date:** | July 01, 2021 |
| **Next Required Review Date:** | March 18, 2022 |