Clinical Policy Title:	loteprednol etabonate
Policy Number:	RxA.757
Drug(s) Applied:	Eysuvis™
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Eysuvis™ is a corticosteroid indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
loteprednol etabonate (Eysuvis™)	Short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.	1-2 drops in each eye four times daily for up to two weeks.	8 drops per day in each eye.

Dosage Forms

- Ophthalmic suspension containing 2.5 mg/mL of loteprednol etabonate.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Dry eye disease (must meet all):

1. Diagnosis of dry eye disease;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with an optometrist or an ophthalmologist;
4. Trial and failure of artificial tears at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Does not exceed 1 bottle per 14 days.

Approval Duration

Commercial: 14 days

Medicaid: 14 days

II. Continued Therapy Approval

A. Dry eye disease (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
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

Commercial: 14 days

Medicaid: 14 days

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

Not Applicable

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
artificial tears (e.g., Visine dry eye relief)	1 to 2 drops in affected eye(s) twice or four times daily	Varies

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Eysuvis™ as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and in mycobacterial infection of the eye and fungal diseases of ocular structures.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Eysuvis™ may be absorbed by soft contact lenses. Contact lenses should be removed prior to instillation and may be reinserted 15 minutes following administration.
- Adverse reactions associated with ophthalmic corticosteroids include elevated intraocular pressure, which may be associated with infrequent optic nerve damage, visual acuity, and field defects, posterior subcapsular cataract formation, delayed wound healing.

References

1. Eysuvis™ Prescribing Information. Watertown, MA: Kala Pharmaceuticals, Inc; October 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a2169d82-4275-4ab6-a1c3-c274080b815c&type=display. Accessed February 3, 2022.
2. IPD Analytics Rx Insights_New Drug Review_ Eysuvis™ 11.2020. Available at:

https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Eysuvis. Accessed February 3, 2022.
3. Xiidra® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8589d376-ac10-4ddb-9c53-2e0c8d5675c4&type=display. Accessed February 3, 2022.
4. Restasis® Prescribing Information. Irvine, CA: Allergan, Inc; July 2017. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8e24af2b-bc1c-4849-94f2-6df950cdca89&type=display. Accessed February 3, 2022.
5. Restasis multidose™ Prescribing Information. Irvine, CA: Allergan, Inc; October 2016. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7224d810-bb96-4682-a942-3355e6e8061a&type=display. Accessed February 3, 2022.
6. Cequa®. Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; March 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=48c3d8a3-4289-4b52-9189-58b48596095c&type=display. Accessed February 3, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	2/3/2022	04/18/2022