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Eysuvis (loteprednol etabonate) Prior Authorization with Quantity Limit Program Summary

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent(s)	Indication(s)	Dosage
Eysuvis™ (loteprednol etabonate) Ophthalmic suspension	Indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease	One to two drops into affected eye(s) four times daily for up to two weeks This product should only be renewed after examination under magnification such as slit lamp and evaluation of the intraocular pressure

CLINICAL RATIONALE

Dry eye disease (also known as dry eye syndrome) is a group of tear film disorders due to reduced tear production or tear film instability, associated with ocular discomfort and/or visual symptoms and inflammatory disease of the ocular surface. The tear film secreting glands and ocular surface function as an integrated system. Disease or dysfunction of this system results in unstable and poorly maintained tear film that causes symptoms of ocular irritation and possible damage to the ocular surface. Dry eye disease may be exacerbated by systemic medications (e.g., diuretics, antihistamines, anticholinergics, systemic retinoids, antidepressants) and rosacea.[2]

Dry eye disease is often associated with Sjogren syndrome, an autoimmune multisystem disorder that most often affects the tear and salivary glands. Tear deficiency may occur in other systemic diseases, such as lymphoma, sarcoidosis, hemochromatosis, and amyloidosis. Dry eye disease may also develop due to systemic viral infections, such as retroviruses, Epstein-Barr virus, and HIV.[2]

The American Academy of Ophthalmology and the Tear Film and Ocular Surface Society (TFOS) categorized dry eye into three severity levels based on symptoms and signs. Because of the nature of the disease, the classifications are imprecise as the characteristics overlap between levels of severity.[2,4,5]

- Mild dry eye: symptoms of irritation, itching, soreness, ocular discomfort, burning or intermittent blurred vision.
- Moderate dry eye: increased discomfort and frequency of symptoms, and negative effect on visual function may become more consistent.
- Severe dry eye: increasing frequency of symptoms that may become constant as well as potentially disabling visual symptoms.

The American Academy of Ophthalmology recommend treating mild dry eye with the following:[2,6]

- Education and environmental modifications
- Elimination of offending topical or systemic medications
- Aqueous enhancement using artificial tear substitutes, gels, or ointment
- Eyelid therapy (warm compresses and eyelid scrubs)
- Treatment of contributing ocular factors such as blepharitis or meibomianitis

- Correction of eyelid abnormality

For treatment of moderate dry eye the following are recommended in addition to mild dry eye treatment options:[2,6]
- Topical anti-inflammatory agents (topical cyclosporine and corticosteroids), systemic omega 3 fatty acids supplements
- Punctal plugs
- Spectacle side shields and moisture chambers

For treatment of severe dry eye the following are recommended in addition to mild and moderate dry eye treatment options:[2,6]
- Systemic cholinergic agonists
- Mucolytic agents
- Autologous serum tears
- Contact lenses
- Permanent punctal occlusion
- Tarsorrhaphy

Because of the inconsistent correlation between reported symptoms and clinical signs as well as the relatively poor specificity and/or sensitivity of clinical tests, patients with suggestive symptoms without signs should be placed on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated. As the severity of the dry eyes increases, aqueous enhancement of the eye using topical agents is appropriate. Emulsions, gels, and ointments can be used. The use of artificial tears may be increased, but the practicality of frequent tear instillation depends on the lifestyle or manual dexterity of the patient. Non-preserved tear substitutes are generally preferable; however, tears with preservatives may be sufficient for patients with mild dry eye and an otherwise healthy ocular surface. When tear substitutes are used frequently and chronically (e.g., more than 4 times a day), non-preserved tears are generally recommended. It is imperative to treat any causative factors that are amenable to treatment.[2]

Anti-inflammatory therapies may be considered in addition to aqueous enhancement therapies. However, since dry eye symptoms tend to wax and wane over long periods of time, the lack of long-term data on the effectiveness of cyclosporine and the costs of longer-term (e.g., annual, lifetime) treatment should be weighed.[2]

Pre-treatment with topical ophthalmic corticosteroids either before or during initiation with a non-glucocorticoid anti-inflammatory agent may provide more rapid improvement in symptoms of dry eye disease and decrease the incidence of severe stinging associated with non-glucocorticoid anti-inflammatory agents.[6] The AAO also notes that topical corticosteroid use for dry eye disease is controversial, but use for induction therapy prior to initiating non-glucocorticoid anti-inflammatory agents as maintenance. Steroids can also be used for acute flare-ups triggered by travel, allergies, respiratory infections, or exposures to environmental irritants with maintenance therapy.[7]

The Sjogren's Syndrome Foundation's Clinical Practice Guidelines on Ocular Management in Sjögren's Patients states the following.[3]
- Management depends upon the nature of the dry and the severity of disease.
- In early disease, tear replacement with topically applied artificial tear or lubricant solutions may be sufficient, but progressive or more severe inflammation of the lacrimal gland and ocular surface occur both as an inciting event in many cases and as a secondary effect as the dry eye disease worsens, called keratoconjunctivitis sicca (KCS), requires the use of dietary supplements (omega 3 essential fatty acids),

anti-inflammatory measures (e.g., topical corticosteroids or cyclosporine), or oral secretagogues.
- Plugging of the lacrimal puncta can be done once the inflammatory component of dry eye is controlled. Control of lid margin (meibomian gland) disease may require topical antibiotic or systemic doxycycline therapy. The most severe cases of dry eye, particularly those unresponsive to more standard therapy, may require use of topical autologous serum or partial closure of the interpalpebral fissure to reduce surface exposure. Scleral contact lenses may be needed to control severe ocular surface damage

Safety[1]
Loteprednol is contraindicated in 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 disease of ocular structures.

References

1. Eysuvis prescribing information. Kala Pharmaceuticals. October 2020.
2. Dry eye syndrome Preferred Practice Pattern. American Academy of Ophthalmology. October 2018. Available at: https://www.aaojournal.org/article/S0161-6420(18)32650-2/pdf Accessed 3/12/2019.
3. Ocular Management in Sjögren's Patients. Sjögren's Syndrome Foundation's Clinical Practice Guidelines. Available at https://www.sjogrens.org/files/research/OcularCPG.pdf. Accessed 3/12/19
4. Craig JP et al. TFOS DEWS II definition and classification report. *Ocul Surf.* 2017;15(3):276-283.
5. Wolffsohn JS et al. TFOS DEWS II diagnostic methodology report. *Ocul Surf.* 2017;15(3):539-574.
6. Jones L et al. TFOS DEWS II management and therapy report. *Ocul Surf.* 2017;15(3):575-628.
7. Weiner, G. (2016, May 05). Savvy steroid use. Retrieved March 10, 2021, from https://www.aao.org/eyenet/article/savvy-steroid-use

Eysuvis (loteprednol etabonate) Prior Authorization with Quantity Limit

TARGET AGENT(S)
Eysuvis™ (loteprednol etabonate)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Eysuvis (loteprednol etabonate)			
0.25% ophthalmic solution	86300035101825	M, N, O, or Y	16.6 mL (2 bottles)/ 90 days

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Initial Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. The patient has a diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca) AND ONE of the following:
    a. The patient has NOT been previously treated with the requested agent AND ONE of the following:
        i. The patient has tried and had an inadequate response to at least ONE generic ophthalmic corticosteroid
        OR
        ii. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent
        OR
        iii. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids that is not expected to occur with the requested agent
    OR
    b. The patient has been previously treated with the requested agent AND ALL of the following:
        i. ONE of the following:
            1. The patient has tried and had an inadequate response to at least ONE generic ophthalmic corticosteroid
            OR
            2. The patient has an intolerance or hypersensitivity to therapy with generic ophthalmic corticosteroids that is not expected to occur with the requested agent
            OR
            3. The patient has an FDA labeled contraindication to ALL generic ophthalmic corticosteroids that is not expected to occur with the requested agent
        AND
        ii. The patient has had clinical benefit with the requested agent
        AND
        iii. The patient's eyes have been examined under magnification (e.g., slit lamp) and the patient's intraocular pressure has been evaluated
    AND
2. The patient does NOT have any FDA labeled contraindications to the requested agent
    AND
3. ONE of the following:

a. The requested quantity (dose) does NOT exceed the program quantity limit
OR
b. ALL of the following:
    i. The requested quantity (dose) is greater than the program quantity limit
    AND
    ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
    AND
    iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: 3 months

Renewal Evaluation
Target Agent(s) will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
   AND
2. The patient has had clinical benefit with the requested agent
   AND
3. The patient's eyes have been examined under magnification (e.g., slit lamp) and the patient's intraocular pressure has been evaluated
   AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
5. ONE of the following:
    a. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    b. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: 3 months