Pharmacy Policy Bulletin: J-0845 Dry Eye Disease Products – Commercial and Healthcare Reform	
Number: J-0845	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0845-013	**Original Date:** 11/07/2018
Effective Date: 07/31/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Cequa (cyclosporine) • Eysuvis (loteprednol etabonate) • Miebo (perfluorohexyloctane) • Restasis (cyclosporine) – *Brand only* • Tryptyr (acoltremon) • Tyrvaya (varenicline) • Vevye (cyclosporine)

FDA-Approved Indication(s):	• Cequa
	  ○ To increase tear production in patients with keratoconjunctivitis sicca (dry eye)
	• Eysuvis
	  ○ Short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease
	• Miebo, Tryptyr, Tyrvaya, Vevye
	  ○ Treatment of the signs and symptoms of dry eye disease
	• Restasis
	  ○ To increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca (dry eye).

Background:	• Restasis, Cequa, and Vevye are ophthalmic calcineurin inhibitor immunosuppressants and relatively selective immunomodulatory drugs. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, topical administration of cyclosporine is thought to act as a partial immunomodulator. The exact mechanism of action is not known. • Miebo is a, preservative-free, topical ophthalmic semifluorinated alkane. It forms a monolayer at the air-liquid interface of the tear film which can be expected to reduce evaporation. The exact mechanism of action for Miebo in dry eye disease is not known.

	• Eysuvis is an ophthalmic corticosteroid which inhibits inflammatory responses such as edema, fibrin deposition, capillary dilation, and leukocyte migration, among others.
	• Tyrvaya is a nasal spray that binds to nicotinic acetylcholine receptors activating the trigeminal parasympathetic pathway resulting in increased production of basal tear film as a treatment for dry eye disease.
	• Tryptyr is a transient receptor potential melastatin 8 (TRPM8) thermoreceptor agonist. TRPM8 thermoreceptor stimulation has been shown to activate trigeminal nerve signaling leading to increased basal tear production.
	• Dry eye disease (also known as keratoconjunctivitis sicca) is a complex, multifactorial disease affecting approximately 20 million people in the United States (US). Dry eye disease refers to a group of disorders of the tear film with mechanisms attributed to either excessive tear evaporation or impaired lacrimal production. These mechanisms lead to inflammation of the ocular surface, symptoms of ocular discomfort, and visual changes. Common eye complaints include dryness, red eyes, irritation, gritty sensation, burning, light sensitivity, and blurred vision.
	• Meibomian gland dysfunction (MGD) is the most common underlying cause of evaporative dry eye disease and occurs more frequently compared to aqueous deficient dry eye disease. Increased tear evaporation, hyperosmolarity, and ocular surface damage are commonly observed with MGD.
	• Miebo may offer an advantage in patients with underlying MGD by targeting tear evaporation, or in those who have failed other treatments as Miebo exhibits a unique mechanism of action.
	• The 2023 American Academy of Ophthalmology Preferred Practice Pattern recommends a four-step approach for treatment of dry eye disease:
	  ○ Step one includes patient education, identification and modification of offending agents, lid hygiene and warm compresses, dietary modifications, environmental changes, and ocular lubricants of various types (lipid-containing supplements if MGD present).
	  ○ Step two includes preservative-free lubricants, tear conservation, overnight treatments, in-office heating and expression of meibomian glands, in-office intense pulsed light therapy for MGD, topical antibiotics, limited duration topical corticosteroids, topical secretagogues, topical nonglucocorticoid immunomodulators (e.g., Restasis [cyclosporine]), topical LFA-1 antagonists (e.g., Xiidra [lifitegrast]), topical water-free lipophilic liquid (perfluorohexyloctane), nasal sprays (e.g., varenicline) cholinergic neuroactivation via the trigeminal parasympathetic pathway, or oral macrolide or tetracycline antibiotics.
	  ○ Step three includes oral secretagogues, autologous or allogeneic serum eye drops, platelet-rich plasma eye drops, blood-based products, and therapeutic contact lens.
	  ○ Step four includes longer duration topical corticosteroids, amniotic membrane grafts, surgical punctal occlusion, and other surgical approaches.
	• The 2023 American Academy of Ophthalmology guidelines specifically recommends lifestyle changes with an adequate trial of artificial tears for mild dry eye.
	• Prescribing Considerations:
	  ○ The safety and effectiveness of Eysuvis, Miebo, Cequa, Restasis, Tryptyr, Tyrvaya or Vevye for treatment of dry eye disease in pediatric patients younger than 18 years (16 years for Restasis) of age have not been established.
	  ○ Eysuvis has warnings and precautions for delayed healing and corneal perforation, intraocular pressure (IOP) increase, cataracts, bacterial

	infections, viral infections, and fungal infections. Eysuvis is only FDA approved for short-term (up to two weeks) treatment. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity, and fields of vision. Initial prescription and each renewal of Eysuvis should be made by a physician only after examination with aid of magnification, such as slit lamp biomicroscopy, and where appropriate, fluorescein staining. Additionally, renewal of Eysuvis should be made by a physician only after examination of the patient and evaluation of the IOP.

Approval Criteria

I. Cequa, Miebo, Tryptyr, Tyrvaya, Vevye

A. Initial Authorization

When a benefit, coverage of Cequa, Miebo, Tryptyr, Tyrvaya, or Vevye may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of dry eye disease (ICD 10: H04.12).
3. The member has experienced therapeutic failure, contraindication, or intolerance to artificial tears.
4. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products, use must be verified by pharmacy claims or documented chart notes **(a. and b.)**:
   a. cyclosporine (generic Restasis)
   b. Xiidra

B. Reauthorization

When a benefit, reauthorization of Cequa, Miebo, Tryptyr, Tyrvaya, or Vevye may be approved when the following criterion is met **(1.)**:

1. The prescriber attests that the member has experienced positive clinical response to therapy.

II. Eysuvis

A. Initial Authorization

When a benefit, coverage of Eysuvis may be approved when all of the following criteria are met **(1., 2., and 3.):**

1. The member is 18 years of age or older.
2. The member has a diagnosis of dry eye syndrome (ICD 10: H04.12).
3. The member has experienced therapeutic failure, intolerance, or contraindication to artificial tears.

B. Reauthorization

When a benefit, reauthorization of Eysuvis may be approved when all of the following criteria are met **(1. through 4.):**

1. The prescriber attests that the member has experienced positive clinical response to therapy.
2. The prescriber attests that the member continues to have symptoms of dry eye syndrome (ICD 10: H04.12).
3. The prescriber attests that member has been reexamined under magnification such as a slit lamp.
4. The prescriber attests that the member's intraocular pressure measurement has been reevaluated.

III. Restasis

A. Initial Authorization

When a benefit, coverage of Restasis may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 16 years of age or older.
2. The member has a diagnosis of dry eye disease (ICD 10: H04.12).
3. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Restasis multidose, the member has experienced contraindication or intolerance to plan-preferred generic cyclosporine ophthalmic emulsion that would not be expected with the brand product. Use must be verified by pharmacy claims or documented chart notes.
   b. If the request is for Restasis single dose, the member has experienced contraindication or intolerance to generic cyclosporine ophthalmic emulsion that would not be expected with the brand product. Use must be verified by pharmacy claims or documented chart notes.

B. Reauthorization

When a benefit, reauthorization of Restasis may be approved when all of the following criteria are met **(1. and 2.)**:

1. The prescriber attests that the member has experienced positive clinical response to therapy.
2. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Restasis multidose, the member has experienced contraindication or intolerance to plan-preferred generic cyclosporine ophthalmic emulsion that would not be expected with the brand product. Use must be verified by pharmacy claims or documented chart notes.
   b. If the request is for Restasis single dose, the member has experienced contraindication or intolerance to generic cyclosporine ophthalmic emulsion that would not be expected with the brand product. Use must be verified by pharmacy claims or documented chart notes.

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans:
  - **Cequa, Miebo, Restasis, Tryptyr, Tyrvaya, Vevye:** If approved, up to a 12 month authorization may be granted.
  - **Eysuvis:** If approved, up to a 1 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; September 2019.

2. Eysuvis [package insert]. Watertown, MA: Kala Pharmaceuticals, Inc.; October 2020.
3. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb; May 2023.
4. Restasis [package insert]. Irvine, CA: Allergan; September 2024.
5. Tryptyr [package insert]. Fort Worth, TX: Alcon Laboratories, Inc.; May 2025.
6. Tyrvaya [package insert]. Princeton, NJ: Oyster Point Pharma, Inc.; February 2024.
7. Vevye [package insert]. Nashville, TN: Harrow Eye, LLC; May 2024.
8. Amescua G, Ahmad S, Cheung AY, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2024 Apr;131(4): P1-P49.
9. American Optometric Association. Dry Eye. Available at: https://www.aoa.org/healthy-eyes/eye-and-vision-conditions/dry-eye?sso=y. Accessed June 11, 2025.
10. Chhadva P, Goldhardt R, Galor A. Meibomian gland disease: the role of gland dysfunction in dry eye disease. *Ophthalmology*. 2017;124(11):20-6