VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmology – Dry Eye Disease – Cyclosporine Products Prior Authorization Policy
- Cequa™ (cyclosporine 0.09% ophthalmic solution – Sun Pharmaceuticals)
- Restasis® (cyclosporine 0.05% ophthalmic emulsion – Allergan, generic)
- Restasis Multidose™ (cyclosporine 0.05% ophthalmic emulsion – Allergan)
- Vevye™ (cyclosporine 0.1% ophthalmic solution – Harrow)

REVIEW DATE: 04/10/2024

OVERVIEW

Ophthalmic cyclosporine products are indicated for the treatment of signs and symptoms of dry eye disease.[1-4] Specifically, ophthalmic cyclosporine emulsion products are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to **ocular inflammation associated with keratoconjunctivitis sicca**.[1,2] Cequa is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).[3] Vevye is indicated for the treatment of the signs and symptoms of dry eye disease.[4]

Dry eye disease refers to a group of disorders of the tear film that are due to reduced tear production or tear instability and are associated with ocular discomfort and inflammatory disease of the ocular surface.[5] Dry eye disease is also known as dry eye syndrome and keratoconjunctivitis sicca.

The safety and efficacy of Restasis have not been established in pediatric patients < 16 years of age.[1,2] Although both Cequa and Vevye are approved for use in patients ≥ 18 years of age per product labeling, these products have the same chemical moiety as Restasis.[1-4]

Guidelines

The American Academy of Ophthalmology (AAO) Dry Eye Syndrome Preferred Practice Pattern® [2024] notes dry eye syndrome is also known as dry eye disease or keratoconjunctivitis sicca.[2] Dry eye is generally classified according to both symptoms and signs (i.e., mild, moderate, or severe); however, there is an emphasis on symptoms over signs. Management of dry eye is listed as a four-step staged approach, but specific therapies may be chosen from any step, regardless of the level of disease severity, depending on provider experience and patient preference. Ophthalmic cyclosporine, as well as other FDA-approved therapies for dry eye disease (Miebo™ [perfluorohexyloctane ophthalmic solution], Tyrvaya® [varenicline nasal spray], and Xiidra® [lifitegrast ophthalmic solution], and Xiidra® [lifitegrast ophthalmic solution]), are noted as Step 2 options in the Preferred Practice Pattern. The AAO notes use of any of these FDA-approved products may lead to improvement of patient symptoms and/or signs but none has been proven more effective than the other in head-to-head trials; there are no direct comparisons in a prospective clinical trial in the literature. The AAO also notes that dry eye disease may develop as a result of systemic inflammatory diseases (e.g., Sjögren syndrome, autoimmune thyroid disease, or rheumatoid arthritis) and ocular surface disease (e.g., herpes simplex virus keratitis).

The AAO Blepharitis Preferred Practice Pattern® (2024) note that blepharitis can be classified according to anatomic location; anterior blepharitis affects the eyelid skin, base of the eyelashes and the eyelash follicles, whereas posterior blepharitis affects the meibomian glands. Blepharitis frequently leads to ocular surface inflammation, including conjunctivitis, functional tear deficiency, and keratitis and may exacerbate symptoms of coexisting ocular surface disease (including allergy and aqueous tear deficiency).[6] Treatment of blepharitis includes use of warm compresses, eyelid cleansing/eyelid massages, topical and/or systemic antibiotics, and ophthalmic anti-inflammatory agents (e.g., corticosteroids, cyclosporine).

The AAO Conjunctivitis Preferred Practice Pattern® guidelines for conjunctivitis (2024) note that dry eye and blepharitis are the most frequent causes of conjunctival inflammation.[7] Ophthalmic cyclosporine can be used to treat dry eye syndrome associated with GVHD and different types of conjunctivitis.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ophthalmic cyclosporine products. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of ophthalmic cyclosporine products is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Dry Eye Disease.** Approve for 1 year if the patient is ≥ 16 years of age.
   Note: Examples of dry eye disease include dry eye syndrome and keratoconjunctivitis sicca.

Other Uses with Supportive Evidence

2. **Dry Eye Conditions due to Systemic Inflammatory Diseases.** Approve for 1 year if the patient is ≥ 16 years of age.
   Note: Examples of systemic inflammatory diseases that could result in dry eye conditions include Sjögren syndrome, autoimmune thyroid disease, rheumatoid arthritis.

3. **Dry Eye Conditions due to Ocular Surface Diseases.** Approve for 1 year if the patient is ≥ 16 years of age.
   Note: Examples of ocular surface diseases that could result in dry eye conditions include blepharitis, conjunctivitis, herpes simplex keratitis, ocular graft-versus-host disease.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of cyclosporine ophthalmic products is not recommended in the following situations:

1. **Concomitant Use with Another Ophthalmic Cyclosporine Product, Tyrvaya (varenicline nasal solution), or Xiidra (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of two (or three) ophthalmic cyclosporine products or the concomitant use of an ophthalmic cyclosporine product with Tyrvaya, or Xiidra.
   Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevye.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Restasis® ophthalmic emulsion 0.05% [prescribing information]. Irvine, CA: Allergan; July 2017.
2. Restasis Multidose™ ophthalmic emulsion 0.05% [prescribing information]. Irvine, CA: Allergan; July 2017.
3. Cequa™ ophthalmic solution [prescribing information]. Cranbury, NJ: Sun Pharmaceutical; July 2022.
4. Vevye™ ophthalmic solution, 0.1%. Nashville, TN: Harrow; August 2023.
5. Amescua G, Ahmad S, Cheung AY, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2024;131(4);P1-P49.
6. Lin A, Ahmad S, Amescua Get al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Blepharitis Preferred Practice Pattern®. *Ophthalmology*. 2024;131(4):P50-P86...
7. Cheung AY, Choi DS, Ahmad S, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Conjunctivitis Preferred Practice Pattern®. *Ophthalmology*. 2024;131(4):P134-P204.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Addition of Vevye (cyclosporine 0.1% ophthalmic solution) to the policy. Revised "**Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca**" to "**Dry Eye Disease**"; this aligns with the terms used in the labeling for Cequa and Vevye. Added a Note that states Examples of dry eye disease includes dry eye syndrome and keratoconjunctivitis sicca. **Conditions Not Recommended for Approval**: Concomitant use of Xiidra was revised to Concomitant use with Miebo, Tyrvaya, or Xiidra. Concomitant use of Cyclosporine Products: Added Vevye.	07/12/2023
Selected Revision	In **Conditions Not Recommended for Approval**, criterion "Concomitant Use of Cyclosporine Products" was removed and added to the criterion "Concomitant Use with Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline nasal spray), or Xiidra (lifitegrast ophthalmic solution)"; the new criterion reads "Concomitant Use with Another Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline nasal spray), or Xiidra (lifitegrast ophthalmic solution)" and the list of cyclosporine products was added as Note.	10/11/2023
Early Annual Revision	In **Conditions Not Recommended for Approval**, Miebo was removed from the criterion "Concomitant Use with Another Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline nasal spray), or Xiidra (lifitegrast ophthalmic solution)" because Miebo can be used concomitantly with these agents.	04/10/2024