



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 – Novaliq)

REVIEW DATE: 07/12/2023; selected revision 10/11/2023

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CIGNA NATIONAL FORMULARY COVERAGE:

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) published a Preferred Practice Pattern® guidelines (2018) for dry eye syndrome.⁵ The AAO 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 classifies dry eye as mild, moderate, or severe, based on signs and symptoms of the disease. Treatment recommendations of dry eye disease are listed in a four-step progression but specific therapies may be chosen from any category, regardless of the level of disease severity, depending on provider experience and patient preference. Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine) are staged as a Step 2 recommendation within the guidelines. The AAO recommends the use of topical cyclosporine as one of the treatment options for dry eye disease related to Sjögren syndrome.

The AAO Preferred Practice Pattern® guidelines for blepharitis (2018) note that blepharitis is a chronic ocular inflammation that may be associated with abnormalities with the Meibomian gland.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 Preferred Practice Pattern® guidelines for conjunctivitis (2018) 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.

- **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 – Novaliq)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Cequa™ (cyclosporine 0.09% ophthalmic solution – Sun Pharmaceuticals)**
- **Restasis® (cyclosporine 0.05% ophthalmic emulsion (Allergan, generic))**
- **Restasis Multidose™ (cyclosporine 0.05% ophthalmic emulsion (Allergan))**
- **Vevey™ (cyclosporine 0.1% ophthalmic solution – Novaliq)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concomitant Use with Another Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), 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 Miebo, Tyrvaya, or Xiidra.

Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevey.

- 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; October 2021.
4. Vevye™ ophthalmic solution, 0.1%. Irvine, CA: Novaliq; May 2023.
5. Akpek E, Amescua G, Farid M, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2019 Jan;126(1):286-334.
6. Amescua G, Akpek EK, Farid M, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Blepharitis Preferred Practice Pattern®. *Ophthalmology*. 2019 Jan;126(1):P56-P93.
7. Varu DM, Rhee MK, Akpek EK, et al. American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Conjunctivitis Preferred Practice Pattern®. *Ophthalmology*. 2019 Jan;126(1):P94-P169.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca: Examples of dry eye conditions due to ocular inflammation associated with keratoconjunctivitis sicca were moved to a Note.</p> <p>Dry Eye Conditions due to Systemic Inflammatory Diseases: Examples of dry eye conditions due to systemic inflammatory diseases were moved to a Note.</p> <p>Dry Eye Conditions due to Ocular Surface Diseases: Examples of dry eye conditions due to ocular surface diseases were moved to a Note.</p>	09/14/2022
Early Annual Revision	<p>Addition of Vevye (cyclosporine 0.1% ophthalmic solution) to the policy.</p> <p>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.</p> <p>Conditions Not Covered : Concomitant use of Xiidra was revised to Concomitant use with Miebo, Tyrvaya, or Xiidra. Concomitant use of Cyclosporine Products: Added Vevye.</p>	07/12/2023
Selected Revision	<p>In Conditions Not Covered, 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.</p>	10/11/2023

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