

PRIOR AUTHORIZATION POLICY

- POLICY:** Ophthalmology – Dry Eye Disease – Cyclosporine Products Prior Authorization Policy
- Cequa™ (cyclosporine topical solution – Sun Pharmaceuticals)
 - Restasis® (cyclosporine topical emulsion – Allergan, generic)
 - Restasis Multidose™ (cyclosporine topical emulsion – Allergan)

REVIEW DATE: 09/14/2022

OVERVIEW

Cyclosporine topical emulsion ophthalmic products are immunosuppressive agents 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} The safety and efficacy of Restasis have not been established in pediatric patients < 16 years of age.

Cequa is a topical solution of cyclosporine, with the same active ingredient and mechanism as Restasis.³ Although Cequa is approved for patients ≥ 18 years of age per product labeling, it has the same active chemical moiety as Restasis, which is approved in patients ≥ 16 years of age.¹⁻³

Guidelines

The American Academy of Ophthalmology (AAO) published a Preferred Practice Pattern (2018) for the treatment of dry eye syndrome.⁴ 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 Sjögren syndrome. The AAO states that topical cyclosporine may be useful in some patients with posterior blepharitis, in active ocular graft versus host disease, and as adjunctive treatment in atopic/vernal conjunctivitis.^{5,6}

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca.**
Approve for 1 year if the patient is ≥ 16 years of age.

09/14/2022

© 2022. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

Note: Examples of dry eye conditions due to ocular inflammation associated with keratoconjunctivitis sicca include dry eye syndrome and dry eye disease.

Other Uses with Supportive Evidence

2. **Dry Eye Conditions due to Systemic Inflammatory Diseases.** Approve for 1 year if the patient is \geq 16 years of age.

Note: Examples of dry eye conditions due to systemic inflammatory diseases include Sjögren syndrome, rheumatoid arthritis, and systemic lupus erythematosus.

3. **Dry Eye Conditions due to Ocular Surface Diseases.** Approve for 1 year if the patient is \geq 16 years of age.

Note: Examples of dry eye conditions due to ocular surface diseases include ocular rosacea, atopic keratoconjunctivitis, acute corneal graft rejection, blepharitis, herpetic stromal keratitis, and conjunctival 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 Xiidra (lifitegrast ophthalmic solution).** There are no data to support the concomitant use of Restasis or Cequa and Xiidra.
2. **Concomitant use of Cyclosporine Products.** There is no evidence to support additive efficacy of combining Restasis and Cequa.
3. 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. 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.
5. 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.
6. 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.

