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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Topical Products	**Original Policy Date:**	October 7, 2016
Subject:	Cyclosporine Ophthalmics	**Page:**	1 of 5

Last Review Date: March 12, 2021

Cyclosporine Ophthalmics

Description

Restasis (cyclosporine ophthalmic emulsion), Cequa (cyclosporine ophthalmic solution)

Background
Cyclosporine ophthalmics are used to treat chronic dry eye as a result of keratoconjunctivitis sicca. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine ophthalmics increase tear production and are thought to act as partial immunomodulators (1-3).

Regulatory Status
FDA-approved indication:

Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs (1).

Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye) (2).

The safety and effectiveness of Restasis ophthalmic emulsion in pediatric patients less than 16 years of age have not been established (1).

The safety and effectiveness of Cequa ophthalmic solution in pediatric patients less than 18 years of age have not been established (2).

Related policies
Eysuvis, Xiidra

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cyclosporine ophthalmics may be considered **medically necessary** for the treatment of chronic dry eye or decreased tear production and if the conditions indicated below are met.

Cyclosprine ophthalmics may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age and older for Restasis **ONLY**
18 years of age and older for Cequa **ONLY**

Diagnosis

Patient must have the following:

1. Chronic dry eye or decreased tear production
    a. Ocular inflammation associated with keratoconjunctivitis sicca
    b. Anti-inflammatory ophthalmic medications may be used concurrently for a short period (2-4 weeks) while transitioning to monotherapy with cyclosporine ophthalmic
    c. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 16 years of age and older for Restasis **ONLY**
18 years of age and older for Cequa **ONLY**

Diagnosis

Patient must have the following:

1. Chronic dry eye or decreased tear production
    a. Patient has had an improvement in symptoms
    b. **NO** concurrent use of anti-inflammatory ophthalmic medications
    c. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Medication	Quantity Limits
Restasis 0.05% single use vials	180 vials every 90 days
Restasis 0.05% multidose bottles	4 (5.5 mL) bottles every 84 days

OR

Medication	Quantity Limits
Cequa 0.09% single use vials	180 vials every 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Cyclosporine ophthalmics are used to treat chronic dry eye as a result of keratoconjunctivitis sicca. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine ophthalmics increase tear

production and are thought to act as partial immunomodulators. The safety and effectiveness of Restasis ophthalmic emulsion in pediatric patients less than 16 years of age have not been established. The safety and effectiveness of Cequa ophthalmic emulsion in pediatric patients less than 18 years of age have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Cyclosporine ophthalmics while maintaining optimal therapeutic outcomes.

References

1. Restasis [package insert]. Irvine, CA: Allergan, Inc.; July 2017.
2. Cequa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; January 2021.
3. Dry Eyes Syndrome Preferred Practice Pattern. American Academy of Ophthalmology. September 2018. Accessed on January 30, 2021.

Policy History

Date	Action
October 2016	New Addition to PA
November 2016	Addition of 5.5 mL multidose bottle and no dual therapy with another legend ophthalmic for the treatment of dry eyes
March 2017	Annual review
September 2018	Annual review and reference update Addition of Cequa to PA, changed policy name to Cyclosporine Ophthalmics
March 2019	Annual review
September 2020	Annual review and reference update
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of Legend Ophthalmic Medications

Generic Name	Brand Name
cyclosporine	Cequa
cyclosporine	Restasis
lifitegrast	Xiidra
loteprednol	Eysuvis