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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Topical Products	**Original Policy Date:**	October 7, 2016
Subject:	Cyclosporine Ophthalmics	**Page:**	1 of 6

Last Review Date: June 16, 2022

Cyclosporine Ophthalmics

Description

Cequa (cyclosporine ophthalmic solution)

Restasis (cyclosporine ophthalmic emulsion)

Verkazia (cyclosporine ophthalmic emulsion)

Background
Cyclosporine is an immunosuppressant agent when administered systemically. Following ocular administration, cyclosporine is thought to act by blocking the release of pro-inflammatory cytokines such as IL-2 (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 is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye) (2).

Verkazia is a calcineurin inhibitor immunosuppressant indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults (3).

The safety and effectiveness of Restasis in pediatric patients less than 16 years of age have not been established. The safety and effectiveness of Cequa in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Verkazia in pediatric patients less than 4 years of age have not been established (1-3).

Related policies
Eysuvis, Tyrvaya, 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.

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

Verkazia may be considered **medically necessary** for the treatment of vernal keratoconjunctivitis (VKC) and if the conditions indicated below are met.

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

Prior-Approval Requirements

Restasis and Cequa only

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)

Verkazia only

Age 4 years of age and older

Diagnosis

Patient must have the following:

1. Vernal keratoconjunctivitis (VKC)
    a. Patient is symptomatic (e.g., itching, photophobia, or mucus discharge)
    b. Inadequate treatment response, intolerance, or contraindication to artificial tears
    c. Inadequate treatment response, intolerance, or contraindication to a topical mast cell stabilizer (such as cromolyn or Alomide) and/or a topical antihistamine (such as azelastine or ketotifen)
    d. **NO** dual therapy with another cyclosporine ophthalmic medication

Prior – Approval *Renewal* Requirements

Restasis and Cequa only

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)

Verkazia only

Age 4 years of age and older

Diagnosis

Patient must have the following:

1. Vernal keratoconjunctivitis (VKC)
    a. Patient has had an improvement in symptoms
    b. **NO** dual therapy with another cyclosporine ophthalmic medication

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

OR

Medication	Quantity Limits
Verkazia single-dose vials	360 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 or to treat vernal keratoconjunctivitis. The safety and effectiveness of Restasis in pediatric patients less than 16 years of age have not been established. The safety and effectiveness of Cequa in pediatric patients less than 18 years of age have not been established. The safety and

effectiveness of Verkazia in pediatric patients less than 4 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. Verkazia [package insert]. Emeryville, CA: Santen Inc.; June 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
March 2022	Annual review and reference update
May 2022	Addition of Verkazia to policy per FEP
June 2022	Annual review. Added Tyrvaya to Appendix 1

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.

Appendix 1 - List of Legend Ophthalmic Medications for Dry Eye

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