

## Restasis (cyclosporine 0.05% ophthalmic emulsion)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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## Summary

Dry eye disease (DED), which is also known as keratoconjunctiva sicca (KCS), is a common disease characterized by ocular discomfort which is related to either reduced tear production or an increased tear evaporation. Symptoms typically include dryness, red eyes, burning, and pruritus (itching) though symptoms are variable. Management of KCS or DED typically includes non-pharmacological management (e.g., frequent blinking, reducing air conditioning/heat, humidifier use), and eye lubricants (e.g., polyethylene glycol or polyvinyl alcohol eye drops and gels). In those with persistent symptoms, providers will typically prescribe topical Restasis (cyclosporine ophthalmic emulsion 0.05%), topical Xiidra (lifitegrast), or other alternative therapies.

Restasis (cyclosporine ophthalmic emulsion 0.05%) is a topical immunosuppressant indicated for increasing tear production in those with decreased tear production, typically associated with ocular inflammation resulting from keratoconjunctivitis sicca, or dry eye syndrome. The reduction in tear production or increased evaporation may arise from conditions such as Sjögren's syndrome, graft-versus-host disease, or other conditions that lead to inflammation. Restasis (cyclosporine ophthalmic emulsion 0.05%) is typically applied twice daily in each eye, with administrations approximately 12 hours apart. It can be used concomitantly with lubricant eye drops, maintaining a 15-minute interval between the application of each product for proper absorption. The safety and efficacy of Restasis (cyclosporine ophthalmic emulsion 0.05%) in pediatric individuals under the age of 16 has not been established.

## Definitions

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Ocular burning" is a sensation of burning or stinging in the eyes, potentially caused by certain medications or eye conditions.

"Keratitis sicca" is another term for keratoconjunctivitis sicca.

"Keratoconjunctivitis sicca" is a condition marked by dryness of the conjunctiva (the membrane lining the eyelids and covering the white part of the eye) and the cornea (the clear, front surface of the eye).

"Pruritus" is an uncomfortable, irritating sensation often resulting in the urge to scratch.

"Punctal plugs" are small devices inserted into the tear ducts to prevent the drainage of tear fluid, thus helping to maintain the moisture on the eye's surface.

"Sjögren's syndrome" is a chronic autoimmune disorder characterized by dryness of the eyes, mouth, and other mucous membranes due to the body's immune system mistakenly attacking its own cells and tissues.

"Xerophthalmia" is a dry eye syndrome caused by a deficiency in vitamin A. It can lead to blindness if not managed.

"[s]" indicates state mandates may apply.

## Clinical Indications

### Medical Necessity Criteria for Clinical Review

#### General Medical Necessity Criteria

The Plan considers Restasis (cyclosporine 0.05% ophthalmic emulsion) medically necessary when ALL of the following criteria are met:

1. The member is 16 years of age or older; *AND*
2. Restasis (cyclosporine 0.05% ophthalmic emulsion) is being prescribed at a dose and frequency that is within FDA approved labeling; *AND*

*The requested medication is being used within the Plan's Quantity Limit of: Restasis (cyclosporine ophthalmic emulsion) 0.05%: 60 vials every 30 days OR Restasis Multidose (cyclosporine ophthalmic emulsion) 0.05%: 1 bottle every 30 days*

3. The member meets the applicable [Medical Necessity Criteria for Initial Clinical Review](#) or [Subsequent Clinical Review](#) listed below.

### Medical Necessity Criteria for Initial Clinical Review

#### Initial Indication-Specific Criteria

#### Dry Eye Disease

The Plan considers Restasis (cyclosporine 0.05% ophthalmic emulsion) medically necessary when ALL of the following criteria are met:

4. The member meets the above [General Medical Necessity Criteria](#); *AND*
5. The member has at least ONE (1) of the following documented diagnosis:
  - a. Dry eye disease, such as:
    - i. Chronic dry eye disease; *or*
    - ii. Keratitis sicca; *or*
    - iii. Keratoconjunctivitis sicca; *or*
    - iv. Xerophthalmia; *or*
    - v. Any other form of dry eye syndrome; *or*
  - b. Dry eye conditions due to systemic inflammatory diseases, such as:
    - i. Sjögren's Syndrome; *or*

- ii. Other systemic inflammatory diseases resulting in dry eye conditions (e.g., autoimmune thyroid disease, rheumatoid arthritis); *or*
- c. Dry eye conditions due to ocular surface diseases, such as:
  - i. Ocular Graft-vs-Host Disease; *or*
  - ii. Corneal Transplant Rejection; *or*
  - iii. Other ocular surface diseases resulting in dry eye conditions (e.g., blepharitis, conjunctivitis, herpes simplex keratitis, meibomian gland dysfunction, ocular rosacea).

If the above prior authorization criteria are met, Restasis (cyclosporine 0.05% ophthalmic emulsion) will be approved for up to 12 months.<sup>[s]</sup>

#### *Continued Care*

#### Medical Necessity Criteria for Subsequent Clinical Review

##### Subsequent medical Necessity Criteria

#### Dry Eye Disease

The Plan considers Restasis (cyclosporine 0.05% ophthalmic emulsion) medically necessary when ALL of the following criteria are met:

1. The member meets the above applicable [General Medical Necessity Criteria](#) and/or [Initial Clinical Review](#); *AND*
2. Chart documentation indicating ONE of the following:
  - a. The member has shown a clinical improvement<sup>†</sup> in symptoms since starting the requested medication; *or*
  - b. The member has experienced disease stability<sup>†</sup> since starting the requested medication.

<sup>†</sup>*Note: Clinical improvement may be characterized by reduction in signs and symptoms such as ocular discomfort, burning, or dryness, and/or an increase in tear production as measured by standardized tests such as Schirmer's test or tear break-up time. Disease stability refers to a halt in disease progression, with signs and symptoms remaining consistent and not worsening over time. These should be supported by the medical documentation.*

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.<sup>[s]</sup>

#### Experimental / Investigational, or unproven<sup>[s]</sup>

Restasis (cyclosporine 0.05% ophthalmic emulsion) for any other indication is considered experimental, investigational, or unproven. Additionally, the safety and efficacy of Restasis (cyclosporine 0.05% ophthalmic emulsion) has not been established in those under the age of 16 years.

## References

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## Clinical Guideline Revision / History Information

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