Oscar Clinical Guideline: Restasis (cyclosporine 0.05% ophthalmic emulsion) (PG025, Ver. 6)

# Restasis (cyclosporine 0.05% ophthalmic emulsion)



## Summary

Restasis (cyclosporine ophthalmic emulsion 0.05%) is a topical immunosuppressant indicated for increasing tear production in patients 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 is generally 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. The safety and efficacy of Restasis in pediatric patients under the age of 16 have not been established.

## Definitions

"**Angioedema**" is a type of swelling occurring under the skin often due to an allergic reaction to various substances such as animal dander, pollen, certain medications, and specific foods.

"**Conjunctival hyperemia**"is a condition characterized by redness of the eyes, which can be attributed to various causes, including certain medications, eye irritants, or eye diseases.

"**Epiphora**" is an overproduction of tears leading to watering of the eyes.

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

"**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.

"**Urticaria**"refers to a skin rash commonly known as hives, often caused by allergic reactions to food, medication, or other irritants. It is marked by raised, itchy bumps on the skin.

## Medical Necessity Criteria for Initial Authorization

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. The member has at least one of the following documented diagnosis:
    a. Chronic dry eye disease***; or***
    b. Keratitis sicca***; or***
    c. Keratoconjunctivitis sicca***; or***
    d. Ocular Graft vs. Host Disease or Corneal Transplant Rejection***; or***
    e. Sjögren's Syndrome***; or***
    f. Xerophthalmia***; AND***

3. Clinical chart documentation is provided for review to substantiate the above listed requirements.

**If the above prior authorization criteria are met, Restasis (cyclosporine 0.05% ophthalmic emulsion) will be approved for 12 months.**

## Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. the member continues to meet the applicable Initial Authorization criteria***; AND***
2. chart documentation indicates **EITHER** of the following:
    a. The member has shown a clinical improvement[⇅] in symptoms since starting the requested medication; ***or***
    b. The member has experienced disease stability[⇅] since starting the requested medication.

[⇅]*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.*

## Experimental or Investigational / Not Medically Necessary

Restasis (cyclosporine 0.05% ophthalmic emulsion) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Additionally, the safety and efficacy of Restasis (cyclosporine 0.05% ophthalmic emulsion) has not been established in patients under the age of 16 years.

## References


1. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. American Academy of Ophthalmology. 2018. Available at: https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018. Accessed June 2020.
2. Malta JB, Soong HK, Shtein RM, et al. Treatment of ocular graft-versus-host disease with topical cyclosporine 0.05%. Cornea. 2010;29(12):1392.
3. Restasis (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc; Updated July 1, 2017.

4. Restasis Multidose (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc; October 2016.
5. Sacchetti M, Mantelli F, Lambiase A, et al. Systematic review of randomised clinical trials on topical ciclosporin A for the treatment of dry eye disease. Brit J Ophthalmology. Aug 2014; 98(8):1016-22.

## Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 6/29/2023, 9/21/2023