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.

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

"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.

Clinical Indications

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:

1. The member is 16 years of age or older; *AND*
2. 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); *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 up to 12 months.

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 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.*

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

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 those 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. American Academy of Ophthalmology Cornea/External Disease Panel. Dry eye Syndrome Preferred Practice Pattern. American Academy of Ophthalmology. 2013. Available at: https://www.aao.org/education/preferred-practice-pattern/dry-eye-syndrome-ppp-2023. Accessed July 17 2025.
3. Amescua G, Ahmad S, Cheung AY, Choi DS, Jhanji V, Lin A, Mian SI, Rhee MK, Viriya ET, Mah FS, Varu DM; American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2024 Apr;131(4):P1-P49. doi: 10.1016/j.ophtha.2023.12.041. Epub 2024 Feb 12. PMID: 38349301.
4. de Paiva CS, Pflugfelder SC, Ng SM, Akpek EK. Topical cyclosporine A therapy for dry eye syndrome. Cochrane Database Syst Rev. 2019;9:CD010051. doi: 10.1002/14651858.CD010051.pub2.
5. 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.
6. McCann P, Abraham AG, Mukhopadhyay A, et al. Prevalence and Incidence of Dry Eye and Meibomian Gland Dysfunction in the United States: A Systematic Review and Meta-analysis. JAMA Ophthalmol. 2022 Dec 1;140(12):1181-1192. doi: 10.1001/jamaophthalmol.2022.4394.
7. Perry HD, Solomon R, Donnenfeld ED, et al. Evaluation of topical cyclosporine for the treatment of dry eye disease. Arch Ophthalmol. 2008;126:1046-1050.doi: 10.1001/archopht.126.8.1046.
8. Restasis (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc; Updated July 1, 2017.
9. Restasis Multidose (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc; October 2016.

10. Roberts CW, Carniglia PE, Brazzo BG. Comparison of topical cyclosporine, punctal occlusion, and a combination for the treatment of dry eye. Cornea. 2007;26:805-809. doi: 10.1097/ICO.0b013e318074e460.
11. 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.
12. Stonecipher KG, Torkildsen GL, Ousler GW, 3rd, et al. The IMPACT study: A prospective evaluation of the effects of cyclosporine ophthalmic emulsion 0.05% on ocular surface staining and visual performance in patients with dry eye. Clin Ophthalmol. 2016;10:887-895.doi: 10.2147/OPTH.S101627.
13. Su MY, Perry HD, Barsam A, et al. The effect of decreasing the dosage of cyclosporine a 0.05% on dry eye disease after 1 year of twice-daily therapy. Cornea. 2011;30:1098-1104. doi: 10.1097/ICO.0b013e318206caee.

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, 9/18/2024, 12/01/2025