Clinical Policy: Cyclosporine (Restasis)

Reference Number: PA.CP.PMN.48
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
Cyclosporine (Restasis®) is a topical immunomodulator.

FDA approved indication
Restasis is 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.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Restasis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Keratoconjunctivitis Sicca (must meet all)**:**

1. Diagnosis of keratoconjunctivitis sicca with suppressed tear production due to ocular inflammation;
2. Failure of artificial tears at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of one ophthalmic corticosteroid agent at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed FDA approved maximum recommended dose (60 vials/ 30 days).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Keratoconjunctivitis Sicca (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose (60 vials/30 days).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food & Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Keratoconjunctivitis sicca	1 drop twice daily in each eye	1 drop twice daily in each eye

VI. Product Availability

Ophthalmic emulsion: 0.5 mg/mL

VII. References

1. Restasis Prescribing Information. Irvine, CA: Allergan, Inc.; July 2017. Available at: https://www.restasis.com/. Accessed January 2018.
2. The International Dry Eye Workshop. Ocul Surf. 2007; 5(2):65-204.
3. American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; October, 2013. Available at: www.aao.org/ppp. Accessed January 2018.
4. Restasis. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: expanded requirement of any OTC wetting agent to artificial tears and anti-inflammatory agent; \ expanded approval duration; reviewed and updated references.	02.02.18	