

***Title: Cyclosporine (Restasis®)***

<b>Origination:</b> 02/25/99	<b>Revised:</b> 05/19/09	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Medication Summary***

- Restasis® (cyclosporine ophthalmic emulsion) 0.05% contains a topical immunomodulator with anti-inflammatory effects. Cyclosporine emulsion is used for the treatment of xerophthalmia (dry eyes) in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. The exact mechanism of action is unknown.

***Reference Statement***

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Eligibility Criteria***

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

***Exclusions***

- If a member has a current ocular infection, Restasis® (cyclosporine ophthalmic emulsion) is contraindicated.

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**Procedure:**

- 1.0 Request for *initial therapy* requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
  - 1.1 Member has a diagnosis of dry eye disease (keratoconjunctivitis sicca); **AND**
  - 1.2 Member has tried and failed an ocular lubricant (i.e., artificial tears, Akwa Tears, Refresh, Systane); **AND**
  - 1.3 Provider is an ophthalmologist, *optometrist* or rheumatologist (or mid-level practitioner under one of these respective specialists); **AND**
  - 1.4 If the Member meets all of the criteria, may approve 60 units per 30 days for up to 12 months.
  
- 2.0 Request for *continuation therapy* beyond the initial authorization period requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying that the Member has shown a favorable response (reduction in signs and symptoms of dry eyes):
  - 2.1 If the Member meets the continuation criterion, may approve 60 units per 30 days for up to 12 months.

**References:**

1. Restasis® Prescribing Information, Allergan, Inc., 2006, Revised January 2008.
2. Gold Standard, Clinical Pharmacology: Restasis® monograph, accessed on March 2009.
3. Rapuano C, Feder R, Jones M, Mah F, Naseri A, Talley-Rostov A, Velazquez A, Weiss J, Musch, D. American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Dry eye syndrome. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 21. [cited 2009 April 13]. Available from: [http://one.aaopt.org/CE/PracticeGuidelines/PPP\\_Content.aspx?cid=65b04ca6-a26d-4454-b27b-46aed841334d](http://one.aaopt.org/CE/PracticeGuidelines/PPP_Content.aspx?cid=65b04ca6-a26d-4454-b27b-46aed841334d).
4. Kunert KS, Tisdale AS, Stern ME, et al. Analysis of topical cyclosporine treatment of patients with dry eye syndrome: effect on conjunctival lymphocytes. Arch Ophthalmol 2000;118:1489-96.
5. Pflugfelder SC, Solomon A, Stern ME. The diagnosis and management of dry eye: a twenty-five-year review. Cornea 2000;19:644-9.
6. Perry HD, Solomon R, Donnenfeld ED, et al. Evaluation of topical cyclosporine for the treatment of dry eye disease. Arch Ophthalmol 2008;126:1046-50.

**Disclaimer Information:**

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Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.