

Medical Affairs Policy & Procedure

Title/Service: Restasis (cyclosporine ophthalmic emulsion)

Revised	
Reviewed	08/26/05, 01/23/09, 04/28/10, 09/16/2011
Developed	08/26/05
Policy Committee Approval	09/16/2011

Description:

Restasis is a prescription medication used to increase tear production for the treatment of dry eye. Restasis contains a topical immunomodulating agent with anti-inflammatory effects.

Indications of Coverage:

Restasis is considered medically necessary when **all** of the following criteria, based on the recommendations of the American Academy of Ophthalmology (AAO), are met:

- A. A thorough eye-related history has been completed that is focused on environmental factors and assesses for diseases in which dry eyes are known to occur;
 - B. An external exam is completed, including a slit lamp biomicroscopy and one or more tests for tear film;
 - C. The tear break up time is abnormal (less than ten seconds), or the Schirmer test is abnormal (less than ten millimeters without anesthetic or less than five millimeters with anesthetic), or the corneal or scleral staining pattern is abnormal and consistent with an abnormal tear film;
 - D. Ophthalmic emulsions that contain the same or similar base solution as that found in Restasis (for example, Bausch and Lomb Soothe) have been used at least three times a day for four weeks along with oral Omega 3 fatty acid supplements, and the signs and symptoms continue.
 - E. If meibomian gland dysfunction is documented, documentation of a trial of doxycycline and compresses is required.
- If criteria are met, treatment may be approved for up to six months, to be added to the treatment for mild dry eye as recommended by the AAO. Subsequent treatment may be approved in one year increments with review of continued therapeutic response and consistent prescription medication use. Consistent use of this medication twice

per day is required for extension of prior authorization, since adequate efficacy has not been demonstrated with less frequent or “as needed” use.

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. The use of Restasis is considered not medically necessary in individuals with active ocular infections.

Documentation Required:

- Office notes
- Test results documenting dry eye
- Prescription medication use data

Rationale:

Restasis is indicated to increase tear production in individuals whose tear production is suppressed due to ocular inflammation associated with eratoconjunctivitis sicca. Inflammation may also be caused by other conditions such as autoimmune disorders and meibomian gland dysfunction. Studies have shown that an increase in omega-3 and/or linoleic acids (available in flaxseed oil) can decrease symptoms due to keratoconjunctivitis sicca, and its use is standard.

Individuals with a confirmed diagnosis of chronic dry eye may eventually stop responding to the use of eye drops and oral omega 3 supplements. Restasis helps increase the eyes’ natural ability to produce tears. Studies have shown that many individuals respond to the use of drops with the same base solution as Restasis.

According to the Preferred Practice Pattern Guidelines of the American Academy of Ophthalmology, dry eye syndrome diagnostic testing includes ocular surface dye evaluation, testing of tear break-up time, and testing of tear production by performing Schirmer’s testing. The treatment includes environmental modification (humidification), elimination of certain medications known to cause or increase dry eye symptoms, artificial tears and ointments, eyelid therapy, and treatment of blepharitis or meibomitis if present. For moderate dry eye, oral omega-3 supplements, corticosteroid drops, treatment with Restasis or punctal plugs may be added. (See Table 4 of the AAO Guidelines.)

Also according to American Academy of Ophthalmology guidelines, if over-the-counter treatments (such as those listed above) do not relieve symptoms, Restasis may be added to the over-the-counter treatments; Restasis takes three to six months to exert an anti-inflammatory effect.

References:

1. Allergan. Restasis (cyclosporine ophthalmic emulsion) 0.05%. Product Information. Irvine, CA: Allergan; Revised: 02/2010. Available at: www.allergan.com/assets/pdf/restasis_pi.pdf. Accessed: 30 Aug 11.
2. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2008. Available at: <http://www.aaopt.org/ppp>. Accessed: 30 Aug 11.
3. Perry HD, Doshi-Carnevale S, Donnenfeld ED, Solomon R, Biser SA, Bloom AH. Efficacy of commercially available topical cyclosporine A 0.05% in the treatment of meibomian gland dysfunction. *Cornea*. 2006 Feb;25(2):171-5.
4. Pflugfelder SC. Antiinflammatory therapy for dry eye. *Am J Ophthalmol*. 2004 Feb; 137(2):337-42.
5. Roberts CW, Carniglia PE, Brazzo BG. Comparison of topical cyclosporine, punctal occlusion, and a combination for the treatment of dry eye. *Cornea*. 2007 Aug;26(7):805-9.

Approved by the Medical Director