

# PRIOR AUTHORIZATION CRITERIA

<b>BRAND NAME</b> (generic)	<b>RESTASIS</b> (cyclosporine ophthalmic emulsion)
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**Status: CVS Caremark Criteria**  
**Type: Initial Prior Authorization**

**Ref# 704-A**

## FDA-APPROVED INDICATION

Restasis is a topical immunomodulator 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.

## COVERAGE CRITERIA

Restasis will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for dry eye disease  
**AND**
- Patient has tried and failed or been intolerant to artificial tears products  
**AND**
- Patient will not be using ophthalmic anti-inflammatory drugs concurrently with the requested drug  
**OR**
- Patient will be using ophthalmic anti-inflammatory drugs concurrently with the requested drug  
**AND**
- The ophthalmic anti-inflammatory drugs will be used concurrently for a short period (2 to 4 weeks) while transitioning to monotherapy with the requested drug

## RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Restasis is a topical immunomodulator 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. The efficacy of Restasis was evaluated in four multicenter, randomized, adequate and well-controlled clinical studies which included approximately 1,200 patients with moderate to severe keratoconjunctivitis sicca. Restasis demonstrated statistically significant increases in Schirmer wetting of 10 mm versus vehicle at six months in patients whose tear production was presumed to be suppressed due to ocular inflammation.<sup>1-3</sup>

The safety and efficacy of Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16.<sup>1-3</sup>

Artificial tear substitutes are included in the categories of dry eye syndrome treatment recommendations.<sup>4</sup> Punctal plugs are included in the categories of dry eye syndrome treatment recommendations.<sup>4</sup> Plug-containing regimens increased wetness initially; cyclosporine appeared to promote long-term ocular surface health. The effects may be additive. Patients with punctal occlusion may benefit from adjunctive cyclosporine.<sup>5</sup>

## REFERENCES

1. Restasis [package insert]. Irvine, CA: Allergan, INC; June 2013.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed November 2016.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed November 2016.
4. Preferred Practice Pattern. Dry Eyes Syndrome. American Academy of Ophthalmology. September 2013.
5. Roberts CW, et al. Comparison of Topical Cyclosporine, Punctal Occlusion, and a Combination for the Treatment of Dry Eye. *Cornea* 2007; 26(7):805-809.



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