PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

RESTASIS
(cyclosporine ophthalmic emulsion)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref# 704-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

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

The requested drug 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 experienced an inadequate treatment response, intolerance, or contraindication to artificial tears products

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.[1-3]

The safety and efficacy of Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16.[1-3]

Artificial tear substitutes are included in the categories of dry eye syndrome treatment recommendations.[4] Punctal plugs are included in the categories of dry eye syndrome treatment recommendations.[4] 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.[5]

REFERENCES

1. Restasis [package insert]. Irvine, CA: Allergan, Inc; July 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 2017.
3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed October 2017.
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.

Written by: UM Development (CT)
Date Written: 02/2010 (client requested)
Revised: (SE) 09/2011 (MDC-1 standard document); (PL) 02/2012; (CT) 09/2012 (CMS requested changes); (MS) 02/2013; (CF) 11/2013, (SE/WW) 11/2014, (LN) 04/2015 (added denial reasons); (KM) 11/2015 (removed punctal plug question); (MS) 11/2016; (DS) 11/2017 (extended DOA)
Reviewed: Medical Affairs (KP) 02/2010, (WF) 09/2011, (KP) 02/2012, 10/2012; (DC) 02/2013; (LCB) 11/2013; (LMS) 02/2014, (DNC) 11/2014, (LCB) 11/2015; (AA) 01/2017; (ME) 11/2017
External Review: 03/2010, 10/2011, 06/2012, 10/2012, 04/2013, 02/2014, 02/2015, 02/2016, 02/2017,12/2017

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for dry eye disease?	Yes	No
2	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to artificial tears products?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	Your plan covers this drug when you have dry eye disease. Your use of this drug does not meet the requirement. This is based on the information we have.
2.	Approve, 36 months	Deny	Your plan covers this drug when you tried artificial tears products and they either did not work for you or you cannot use them. Your use of this drug does not meet the requirement. This is based on the information we have.