

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## cyclosporine ophthalmic

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Cequa (cyclosporine ophthalmic solution) 0.09%	May be subject to quantity limit
Restasis (cyclosporine ophthalmic emulsion) 0.05%	

### APPROVAL CRITERIA

Requests for Cequa (cyclosporine ophthalmic solution) or Restasis (cyclosporine ophthalmic emulsion) may be approved if the following criteria are met:

- I. Individual is 16 years of age or older for Restasis (cyclosporine ophthalmic emulsion) dose form (multi-dose bottle or single-dose vial) requests; **OR**
- II. Individual is 18 years of age or older for Cequa (cyclosporine ophthalmic solution) requests;

### **AND**

- III. Individual is using to treat moderate to severe dry eye disease (AAO 2018); **AND**
- IV. Individual has an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO 2018):
  - A. Tear break-up time (less than 10 seconds); **OR**
  - B. Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes; **OR**
  - C. Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes); **OR**
  - D. Fluorescein clearance test/tear function index; **OR**
  - E. Tear osmolarity (indicating tear film instability); **OR**
  - F. Tear lactoferrin concentrations in the lacrimal gland (decreased); **OR**
  - G. Matrix metalloproteinase-9 (MMP-9) test;

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**AND**

- V. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to one artificial tear agent (AAO, 2013);

**AND**

- VI. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to Xiidra (lifitegrast ophthalmic solution);

**OR**

- VII. Individual has a known hypersensitivity to any ingredient in Xiidra which is not also present in the requested non-preferred agent (Cequa or Restasis).

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 16, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. November 2018. Available from: <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed on: January 16, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.