

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

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%	Commercial lines of business: N/A Medicaid lines of business: May be subject to quantity limit

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**

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G. Matrix metalloproteinase-9 (MMP-9) test;

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).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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.

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