

| Market Applicability | | | | | | | | | | | | | | |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|
| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | X | NA | NA | X | NA | 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; **AND**
- II. Individual is using to treat moderate to severe dry eye disease (AAO 2013); **AND**
- III. Individual has an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO, 2013):
 - 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);

AND

- IV. 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);

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.

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

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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 Xiidra (lifitegrast ophthalmic solution);

OR

VI. Individual has a known hypersensitivity to any ingredient in Xiidra which is not also present in Cequa or Restasis.

Note: Increased tear production has not been seen in individuals concurrently using topical anti-inflammatory drugs or using punctual plugs.

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

Key References:

American Academy of Ophthalmology Cornea/External Disease Panel. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. September 2013. Available from: <http://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp--2013>. Accessed on: January 27, 2017.

National Eye Institute (NEI). Facts About Dry Eye. Department of Health and Human Services and the National Institutes of Health website. Available from: <https://nei.nih.gov/health/dryeye/dryeye>. Last reviewed on: February 2013. Accessed on: January 27, 2017

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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