

Clinical Pharmacy Program Guidelines for Dry Eye Disease

Program	Prior Authorization
Medication	Restasis [®] (cyclosporine 0.05% ophthalmic emulsion), Restasis Multidose (cyclosporine 0.05% ophthalmic emulsion), Xiidra [™] (lifitegrast 5% ophthalmic solution)
Issue Date	11/2016
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Restasis[®] (cyclosporine 0.05% ophthalmic emulsion) and Restasis Multidose (cyclosporine 0.05% ophthalmic emulsion) are indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Xiidra[™] (lifitegrast 5% ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

2. Coverage Criteria:

<p>A. Restasis or Restasis Multidose</p> <p>1. Initial Authorization</p> <p>a. Restasis or Restasis Multidose will be approved based on all of the following:</p> <p>(1) Tear deficiency associated with ocular inflammation due one of the following:</p> <p>(a) Moderate to severe keratoconjunctivitis sicca (KCS)</p> <p style="text-align: center;">-OR-</p> <p>(b) Moderate to severe Dry Eye Disease (DED)</p> <p style="text-align: center;">-AND-</p> <p>(2) Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g.: LASIK)</p>
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-AND-

- (3) History of failure to at least one OTC ocular lubricants/artificial tear solutions (e.g.: Systane, Akwa Tears, Refresh Optive, Soothe)

-AND-

- (4) Prescribed by or in consultation with **one** of the following:
 - (a) Ophthalmologist
 - (b) Optometrist
 - (c) Rheumatologist

-AND-

- (5) History of failure, contraindication, or intolerance to Xiidra

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Restasis or Restasis Multidose** will be approved based on the following criterion:

- (1) Patient has demonstrated clinically significant improvement with therapy

Authorization will be issued for 12 months.

B. Xiidra

1. Initial Authorization

- a. **Xiidra** will be approved based on **all** of the following:

- (1) Tear deficiency associated with ocular inflammation due **one** of the following:

- (a) Moderate to severe keratoconjunctivitis sicca (KCS)

-OR-

- (b) Moderate to severe Dry Eye Disease (DED)

-AND-

- (2) Not prescribed to manage dry eyes peri-operative elective eye surgery (e.g.: LASIK)

-AND-

- (3) History of failure to at least one OTC ocular lubricants/artificial tear solutions (e.g.: Systane, Akwa Tears, Refresh Optive, Soothe)

-AND-

- (4) Prescribed by or in consultation with **one** of the following:
- (a) Ophthalmologist
 - (b) Optometrist
 - (c) Rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Xiidra** will be approved based on the following criterion:

- (1) Patient has demonstrated clinically significant improvement with therapy

Authorization will be issued for 12 months.

3. References:

1. Restasis [Prescribing Information].: Allergan, Inc. Irvine, CA. June 2013.
2. Restasis MultiDose [Prescribing Information]. Allergan, Inc. Irvine, CA. October 2016.
3. Xiidra [Prescribing Information]. Shire US Inc. Lexington, MA. July 2016.
4. American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; October, 2013. Available at: www.aao.org/ppp. Accessed February 3, 2014

Program	Prior Authorization
Change Control	
Date	Change
11/2016	New program
2/2017	Separated Xiidra and Restasis into their own sections. Added step through Xiidra for Restasis.
3/2017	Changed initial authorization durations to 12 months
9/2017	Annual Review. Added Restasis Multidose. Updated references.