

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), Cequa (cyclosporine 0.09% ophthalmic solution)
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, South Carolina
Issue Date	11/2016
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Cequa™ (cyclosporine 0.09% ophthalmic solution), 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.

2. Coverage Criteria:

<p>A. Cequa, Restasis or Restasis Multidose</p> <p>1. <u>Initial Authorization</u></p> <p>a. Cequa, Restasis or Restasis Multidose will be approved based on <u>all</u> of the following:</p> <p>(1) Tear deficiency associated with ocular inflammation due to <u>one</u> of the following:</p> <p>(a) Moderate to severe keratoconjunctivitis sicca</p> <p style="text-align: center;">-OR-</p> <p>(b) Moderate to severe dry eye disease</p> <p style="text-align: center;">-AND-</p>

(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 artificial tear product (e.g.: Systane[®] Ultra, Akwa[®] Tears, Refresh Optive[®], Soothe[®] XP)

-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. **Cequa, 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 to **one** of the following:

- (a) Moderate to severe keratoconjunctivitis sicca

-OR-

- (b) Moderate to severe dry eye disease

-AND-

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

<p>-AND-</p> <p>(3) History of failure to at least one OTC artificial tear product (e.g.: Systane® Ultra, Akwa® Tears, Refresh Optive®, Soothe®)</p> <p style="text-align: center;">-AND-</p> <p>(4) Prescribed by or in consultation with one of the following:</p> <p style="margin-left: 40px;">(a) Ophthalmologist</p> <p style="margin-left: 40px;">(b) Optometrist</p> <p style="margin-left: 40px;">(c) Rheumatologist</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Xiidra will be approved based on the following criterion:</p> <p style="margin-left: 40px;">(1) Patient has demonstrated clinically significant improvement with therapy</p> <p>Authorization will be issued for 12 months.</p>
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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Cequa [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; September 2019.
2. Restasis [prescribing information]. Irvine, CA: Allergan, Inc.; July 2017.
3. Restasis MultiDose [prescribing information]. Irvine, CA: Allergan, Inc.; October 2016.
4. Xiidra [prescribing information]. Hanover NJ: Novartis Pharmaceuticals Corporation: November 2019.
5. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern 2018. Accessed March 2, 2020.

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.
9/2018	Annual review. Administrative updates and updated references.
3/2019	Added Cequa and updated references.
4/2020	Annual review, updated references.