Pharmacy Policy

**Restasis®, Xiidra™**

**Policy Number:** 9.022  
**Version Number:** 9.0  
**Version Effective Date:** 03/1/2018

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**Product Applicability**

- [x] All Plan Products

**Well Sense Health Plan**

- New Hampshire Medicaid
- NH Health Protection Program

**Boston Medical Center HealthNet Plan**

- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options

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Note: Disclaimer and audit information is located at the end of this document.

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**Policy Summary**

The Plan will authorize coverage of Restasis® and Xiidra™ when appropriate criteria are met.

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**Description of Item or Service**

Restasis® (cyclosporine) is a topical ophthalmic emulsion FDA-approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. It is thought to act as a partial immunomodulator with anti-inflammatory effects, although the exact mechanism is currently unknown.

Xiidra™ (lifitegrast) is an ophthalmic solution for the treatment of the signs and symptoms of dry eye disease (DED). Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease. The most common side effects of Xiidra include eye irritation, discomfort or blurred vision and an unusual taste sensation (dysgeusia). Dry eye disease does not routinely occur in children. Safety and efficacy in pediatric patients below the age of 17 years has not been studied.

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Dry Eye Disease (DED), Keratoconjunctivitis sicca (KCS), or dry eye syndrome, is characterized by inadequate tear film protection of the cornea. Ocular inflammation is a common cause of KCS, especially in autoimmune diseases such as Sjögren’s Syndrome and Systemic Lupus Erythematosus (SLE). As a result, there is diminished lacrimal and salivary gland function with resultant sicca symptoms, including dry eye. Graft versus Host Disease (GVHD) also has ocular manifestations including KCS. The goals of therapy include symptom relief and prevention of keratitis, corneal ulceration, or scarring of the ocular surface. Currently, the mainstay of treatment for most patients is the use of replacement fluids, such as artificial tears and ocular lubricant products. There are a variety of replacement fluid products available over-the-counter and the choice of product must take into account patient-specific needs.

The use of topical cyclosporine has been studied in the management of corneal transplant rejection and studies have shown benefits of topical cyclosporine in the prevention or treatment of graft rejection. The benefits seen have not been demonstrated to be more effective than ophthalmic corticosteroids, which are currently the mainstay of therapy.

The information reviewed has not demonstrated that Restasis® be considered a first line therapy in the management of these conditions. Furthermore, it is important to have a confirmed diagnosis to determine appropriateness of Restasis® use in these ocular inflammatory conditions.

**Policy**

The Plan may authorize coverage of Restasis® and Xiidra™ for treatment of specific conditions when the following criteria are met:

**Prior Authorization**

A prior authorization request will be required for all prescriptions for Restasis® and Xiidra™. These requests will be approved when the following criteria are met:

**Initial Therapy (Duration of approval – Maximum of 6 months)**

**Restasis®**

Documentation of the following:
1. Age is 16 years or older; **AND**
2. Restasis is prescribed by or in collaboration with an ophthalmologist, optometrist, or rheumatologist; **AND**
3. A confirmed diagnosis of moderate-severe chronic ocular inflammation associated with keratoconjunctivitis sicca; **AND**
4. An inadequate response or intolerance to a trial of at least 2 artificial tears or ocular lubricant products in the past 120 days; **AND**
5. Member is not currently taking topical anti-inflammatory drugs or using punctal plugs; **OR**

1. Age is 16 years or older; **AND**

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2. There is a high risk for corneal transplant rejection; **AND**  
3. An inadequate response, intolerance, or contraindication to a trial of an ophthalmic corticosteroid or topical cyclosporine is needed as an adjunct to an ophthalmic corticosteroid

**Xiidra™**

Documentation of the following:  
1. Age is 17 years or older; **AND**  
2. Xiidra is prescribed by or in collaboration with an ophthalmologist, optometrist, or rheumatologist; **AND**  
3. A confirmed diagnosis of moderate to severe dry eye disease; **AND**  
4. An inadequate response or intolerance to a trial of at least 2 artificial tears or ocular lubricant products in the past 120 days

**Continuation of therapy** *(Duration of approval – Maximum of 12 months)*

Documentation of the following:  
1. A diagnosis of dry eye disease, moderate-severe keratoconjunctivitis sicca or corneal transplant rejection requiring continued treatment; **AND**  
2. There has been a clinical response to therapy without adverse events.

**Quantity Limitations Apply – See Appendix A**

**Limitations**

BMC HealthNet Plan will **not** approve coverage of Restasis® or Xiidra™ in the following instances:

- When the above criteria are not met.

**Clinical Background Information and References**


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### Appendix A – Quantity Limitations

<table>
<thead>
<tr>
<th>Medication Name and Strength</th>
<th>Maximum Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restasis®</td>
<td>60 single use vials / 30 days</td>
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<tr>
<td>Xiidra™</td>
<td>60 single use containers / 30 days</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
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</thead>
<tbody>
<tr>
<td>07/12/2009</td>
<td>11/12/2009</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
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### Policy Revisions History

<table>
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<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>11/11/2010</td>
<td>P&amp;T Annual Review – Updated criteria to require prescribing by appropriate specialist, addition of criteria for continuation of therapy</td>
<td>03/01/2011</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/10/2011</td>
<td>P&amp;T Annual Review – Removed requirement of documentation of etiology of KCS, required appropriate specialist for continuation of therapy, changed approval duration for continuation to one year.</td>
<td>03/01/2012</td>
<td>P&amp;T Committee</td>
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<tr>
<td>11/08/2012</td>
<td>P&amp;T Annual Review – Added intolerance</td>
<td>03/01/2013</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/14/2013</td>
<td>P&amp;T Annual Review – Added requirement of no concurrent treatment of topical anti-inflammatory drugs or using punctal plugs</td>
<td>03/01/2014</td>
<td>P&amp;T Committee</td>
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<table>
<thead>
<tr>
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<th>Description</th>
<th>Effective Date</th>
<th>Committee</th>
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<tr>
<td>12/13/2013</td>
<td>Policy applied to ConnectorCare/Qualified Health Plan</td>
<td>01/01/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/13/2014</td>
<td>P&amp;T Annual Review, updated criteria to allow for Restasis® to be prescribed in collaboration with an optometrist, ophthalmologist, or rheumatologist</td>
<td>03/02/2015</td>
<td>P&amp;T Committee NH DHHS</td>
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<tr>
<td>11/12/2015</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>03/01/2016</td>
<td>P&amp;T Committee NH DHHS</td>
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<tr>
<td>11/10/2016</td>
<td>P&amp;T Annual Review, updated policy title to reflect addition of Xiidra; new criteria and QL added for Xiidra.</td>
<td>03/01/2017</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>11/09/2017</td>
<td>P&amp;T Annual Review, no criteria changes required</td>
<td>03/1/2018</td>
<td>P&amp;T Committee NH DHHS</td>
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**Next Review Date**

11/10/2018

**Other Applicable Policies**

9.002 Mandatory Generic Substitution Program
9.015 Quantity Limitation Program

**Reference to Applicable Laws and Regulations, If Any**

N/A

**Disclaimer Information**

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over

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these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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