Pharmacy Medical Policy
Topical Ocular Hydrating Agents

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Policy Number: 426
BCBSA Reference Number: None

Related Policies
- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy #621A

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

<table>
<thead>
<tr>
<th>☑ Prior Authorization</th>
<th>☐ Step Therapy</th>
<th>☐ Quality Care Dosing</th>
<th>☑ Rx</th>
<th>☐ MED</th>
</tr>
</thead>
</table>

To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration
Please refer to the chart below for the formulary and step status of the medications affected by this policy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
<th>Standard</th>
<th>Formulary Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cequa™</strong> (cyclosporine)</td>
<td></td>
<td></td>
<td>Not Covered</td>
</tr>
<tr>
<td>Cyclosporine Single use vials</td>
<td></td>
<td></td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Eysuvis™</strong> (loteprednol etabonate)</td>
<td></td>
<td></td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Restasis®</strong> (cyclosporine) Single use vials</td>
<td></td>
<td></td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Restasis®</strong> Multidose (cyclosporine)</td>
<td></td>
<td></td>
<td>Not Covered</td>
</tr>
<tr>
<td><strong>Tyrvaya nasal spray™</strong> (varenicline)</td>
<td></td>
<td></td>
<td>Not Covered</td>
</tr>
<tr>
<td><strong>Verkazia®</strong> (cyclosporine)</td>
<td></td>
<td></td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Xiidra™</strong> (lifitegrast)</td>
<td></td>
<td></td>
<td>PA Required</td>
</tr>
</tbody>
</table>

We may cover **Cyclosporine** Single use vials for the short-term treatment of suppressed tear production due to keratoconjunctivitis sicca-associated ocular inflammation when **all** the following criteria are met:

- Age 16 years of age or older, **AND**
- Member has a definite diagnosis of moderate or severe keratoconjunctivitis sicca, **AND**
- Prescribed by a board-certified ophthalmologist or board eligible ophthalmologist **OR** Prescribed by a board-certified optometrist or board eligible optometrist.

**Note:** If approved the Prior Authorization will be granted for up to one (1) year.

We may cover **Xiidra™** (lifitegrast, ophthalmic) for the treatment of the signs and symptoms of dry eye disease (DED) when **all** the following criteria are met:

- Age 17 years of age or older, **AND**
- Member has a definite diagnosis of moderate or severe dry eye disease (DED), **AND**
- Prescribed by a board-certified ophthalmologist or board eligible ophthalmologist **OR** Prescribed by a board-certified optometrist or board eligible optometrist.

**Note:** If approved the Prior Authorization will be granted for up to one (1) year.

We may cover **Cequa™** (cyclosporine, ophthalmic), **Restasis®** Multidose (cyclosporine, ophthalmic), and **Restasis®** (cyclosporine, ophthalmic) Single use vials, **Tyrvaya nasal spray™** (varenicline) for the short-term treatment of suppressed tear production due to keratoconjunctivitis sicca-associated ocular inflammation when **all** the following criteria are met:

- Age 18 years of age or older, **AND**
- There are BCBSMA paid claims of both **Xiidra™** (lifitegrast) **AND** **Cyclosporine** (Single use vials are on the formulary whereas the Multidose vials are not on the formulary, but either would qualify) or previous treatment with both, **AND**
- Member has a definite diagnosis of moderate or severe keratoconjunctivitis sicca, **AND**
- Prescribed by a board-certified ophthalmologist or board eligible ophthalmologist **OR** Prescribed by a board-certified optometrist or board eligible optometrist.

**Note:** If approved the Prior Authorization will be granted for up to one (1) year.

We may cover **Eysuvis™** (loteprednol etabonate, ophthalmic) the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease when **all** the following criteria are met:

- Age 18 years of age or older, **AND**
- The patient does not have glaucoma or any other eye issues like infection, **AND**
- Prescribed by a board-certified ophthalmologist or board eligible ophthalmologist **OR** Prescribed by a board-certified optometrist or board eligible optometrist.

**Note:** If approved the Prior Authorization will be granted for 2 weeks.

We may cover **Verkazia®** (cyclosporine) for the treatment of vernal keratoconjunctivitis (VKC) in children and adults. when **all** the following criteria are met:

- Age 4 years of age or older, **AND**
- Member has a definite diagnosis of moderate or severe vernal keratoconjunctivitis (VKC).
Note: If approved the Prior Authorization will be granted for up to one (1) year.

Restasis® (cyclosporine, ophthalmic) has safety data to include ages 16 and older.

*Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and step criteria below are met.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

We do not cover Restasis® (cyclosporine, ophthalmic) for other conditions not listed above.

Individual Consideration

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.
### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/2023</td>
<td>Clarified FE criteria when using cyclosporin and updated IC section to align with 118E MGL § 51A.</td>
</tr>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>6/2023</td>
<td>Updated Criteria for Cyclosporine, Xiidra ™, and Eysuvis ™ and added Auth lengths for the drug groupings.</td>
</tr>
<tr>
<td>7/2022</td>
<td>Updated to include Verkazia to the policy.</td>
</tr>
<tr>
<td>4/2022</td>
<td>Updated to add Generic Restasis ® and move Restasis ® to a non-preferred status.</td>
</tr>
<tr>
<td>2/2022</td>
<td>Updated to add Tyrvaya nasal spray™ to the policy.</td>
</tr>
<tr>
<td>4/2021</td>
<td>Clarified age for Xiidra ™.</td>
</tr>
<tr>
<td>1/2021</td>
<td>Updated to add Eysuvis™ to the policy.</td>
</tr>
<tr>
<td>1/2020</td>
<td>Updated criteria for Restasis ® Multidose to not covered.</td>
</tr>
<tr>
<td>10/2019</td>
<td>Updated to clarify Cequa ™ coverage</td>
</tr>
<tr>
<td>2/2019</td>
<td>Updated to add Cequa ™ to the policy.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>11/2016</td>
<td>Updated to add Xiidra ™ to the policy.</td>
</tr>
<tr>
<td>7/2014</td>
<td>Updated policy to include prior use of over the counter preparations, requiring a diagnosis of moderate or severe keratoconjunctivitis sicca, and requiring prescription by a board/eligible ophthalmologist or board/eligible optometrist. Also to remove Blue Value from policy.</td>
</tr>
<tr>
<td>8/2013</td>
<td>Reviewed and updated drug sample exclusion language.</td>
</tr>
<tr>
<td>1/2013</td>
<td>New policy effective 1/1/13.</td>
</tr>
</tbody>
</table>

### References


**To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:**