Cyclosporine Ophthalmics

Description

Restasis (cyclosporine ophthalmic emulsion), Cequa (cyclosporine ophthalmic solution)

Background
Cyclosporine ophthalmics are used to treat chronic dry eye as a result of keratoconjunctivitis sicca. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine ophthalmics increase tear production and are thought to act as partial immunomodulators (1-3).

Regulatory Status
FDA-approved indication:

Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs (1).

Cequa ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye) (2).

The safety and efficacy of Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16. The safety and efficacy of Cequa ophthalmic solution have not been established in pediatric patients below the age of 18 (1-2).
Related policies
Xiidra

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cyclosporine ophthalmics may be considered **medically necessary** for the treatment of chronic dry eyes and if the conditions indicated below are met.

Cyclosporine ophthalmics may be considered **investigational** for all other indications.

**Prior-Approval Requirements**

**Age**

16 years of age and older for Restasis **ONLY**
18 years of age and older for Cequa **ONLY**

**Diagnosis**

Patient must have the following:

1. Chronic dry eye or decreased tear production
   a. Ocular inflammation associated with keratoconjunctivitis sicca
   b. Anti-inflammatory ophthalmic medications may be used concurrently for a short period (2-4 weeks) while transitioning to monotherapy with cyclosporine ophthalmic
   c. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

**Prior – Approval ** Renewal **Requirements**

**Age**

16 years of age and older for Restasis **ONLY**
18 years of age and older for Cequa **ONLY**
Diagnosis

Patient must have the following:

1. Chronic dry eye or decreased tear production
   a. **NO** concurrent use of anti-inflammatory ophthalmic medications
   b. Patient has had an improvement in symptoms
   c. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restasis 0.05% single use vials</td>
<td>180 vials every 90 days</td>
</tr>
<tr>
<td>Restasis 0.05% multidose bottles</td>
<td>4 (5.5 mL) bottles every 84 days</td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cequa 0.09% single use vials</td>
<td>180 vials every 90 days</td>
</tr>
</tbody>
</table>

Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary

Cyclosporine ophthalmics are used to treat chronic dry eye as a result of keratoconjunctivitis sicca. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, cyclosporine ophthalmics increase tear production and are thought to act as partial immunomodulators. The safety and efficacy of
Restasis ophthalmic emulsion have not been established in pediatric patients below the age of 16. The safety and efficacy of Cequa ophthalmic solution have not been established in pediatric patients below the age of 18 (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Cyclosporine ophthalmics while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2016</td>
<td>New Addition to PA</td>
</tr>
<tr>
<td>November 2016</td>
<td>Addition of 5.5 mL multidose bottle and no dual therapy with another legend ophthalmic for the treatment of dry eyes</td>
</tr>
<tr>
<td>March 2017</td>
<td>Annual Review</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review and reference update Addition of Cequa to PA, changed policy name to Cyclosporine Ophthalmics</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.
### Appendix 1 - List of Legend Ophthalmic Medications

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>cyclosporine</td>
<td>Cequa</td>
</tr>
<tr>
<td>cyclosporine</td>
<td>Restasis</td>
</tr>
<tr>
<td>lifitegrast</td>
<td>Xiidra</td>
</tr>
</tbody>
</table>