RESTASIS® (cyclosporine)
Pharmacy Coverage Policy

P&T Review Date: 03/25/2015
UMC Revision Date: 02/12/2015
Reviewer Initials: LH
Effective Date: 05/15/2015

Policy type: PA with QL, QL only
Program type: Standard
Specialty: No
Line of Business: Commercial

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>GPI</th>
<th>Drug Class</th>
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</thead>
<tbody>
<tr>
<td>RESTASIS</td>
<td>cyclosporine</td>
<td>86720020001620</td>
<td>Ophthalmic immunosuppressant agent</td>
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</tbody>
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CRITERIA FOR COVERAGE/NONCOVERAGE

RESTASIS® (cyclosporine ophthalmic emulsion) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The patient has a diagnosis of keratoconjunctivitis sicca (dry eye) or Sjogren syndrome with suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests:
  - Schirmer test (aqueous tear production and clearance)
  - Tear break-up time
  - Ocular surface dye staining
  - Tear film osmolarity
  - Fluorescein clearance test/ tear function test

AND

- The patient has tried and had an inadequate response or intolerance to at least one over-the-counter ocular lubricant used at an optimal dose and frequency for at least two weeks (e.g., artificial tears, lubricating gels/ointments, etc.)

AND

- The patient has tried and had an inadequate response, intolerance or contraindication to a topical ophthalmic corticosteroid

AND

- RESTASIS will not be used in patients with punctal plugs

AND

- The patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDS)

OR

- Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with Restasis

Quantity Limit:

RESTASIS (cyclosporine ophthalmic emulsion) is subject to a quantity limit of 60 unit doses per month (2 trays of 30 vials each).
Reauthorization Criteria and Duration:
Authorization for continued use shall be reviewed at least every 12 months to confirm the patient has experienced an objective response to therapy (e.g., increased tear production or improvement in dry eye symptoms) and will not be using Restasis with topical ophthalmic anti-inflammatory drugs or punctal plugs.

RESTASIS (cyclosporine ophthalmic emulsion) is considered experimental/investigational for conditions not listed in this coverage policy section.