Medication Policy Manual

Policy No: dru472

Topic: High-cost medications for dry eye disease:
- lifitegrast ophthalmic solution 5% (Xiidra®)
- cyclosporine ophthalmic emulsion 0.05% (Restasis®)

Date of Origin: December 16, 2016

Committee Approval Date: December 16, 2016

Next Review Date: December 2017

Effective Date: January 1, 2017

IMPORTANT REMINDER
This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of this Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description
Lifitegrast ophthalmic (Xiidra) and cyclosporine ophthalmic (Restasis) are topical medications used in the treatment of dry eye disease (DED).
Policy/Criteria

I. Most contracts require prior authorization approval of high-cost medications for DED prior to coverage. High-cost medications for DED (as listed in Table 1) may be considered medically necessary when criteria A and B below are met.

A. A diagnosis of dry eye disease established by or in consultation with a specialist in ophthalmology or optometry.

AND

B. Artificial tears have been ineffective, not tolerated, or are contraindicated.

II. Administration, Quantity Limitations, and Authorization Period

A. OmedaRx considers high-cost medications for DED to be a self-administered medications.

B. When prior authorization is approved, high-cost medications for DED may be authorized in quantities outlined in Table 1.

C. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Table 1. High-Cost Medications for DED

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>lifitegrast ophthalmic (Xiidra)</td>
<td>60 single-use vials per 30 days</td>
</tr>
<tr>
<td>cyclosporine ophthalmic (Restasis)</td>
<td>60 single-use vials per 30 days</td>
</tr>
<tr>
<td>cyclosporine ophthalmic multidose</td>
<td>1 bottle (5.5mL) per 30 days</td>
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III. Concurrent use of more than one high-cost medications for DED is considered investigational.
Position Statement

Summary
- The intent of this policy is to allow coverage of high-cost medications for dry eye disease (DED) in patients with a confirmed diagnosis, when artificial tears are not effective, not tolerated, or are contraindicated.
- DED is also known as keratoconjunctivitis sicca and dry eye syndrome.
- Over-the-counter (OTC) artificial tears are a best value treatment for DED. Clinical guidelines support the use of artificial tears as first-line therapy with high cost medications being added if additional symptom relief is required.
- There is no reliable evidence to support the use of lifitegrast ophthalmic (Xiidra) or cyclosporine ophthalmic (Restasis) in ophthalmic conditions other than DED.
- Concurrent use of high-cost medications for DED is considered investigational. There is no evidence demonstrating the safety or effectiveness of these medications used in combination.

Clinical Efficacy
- Artificial tears improve the frequency and severity of symptoms in patients with DED compared to placebo. There is insufficient evidence to determine if one formulation of artificial tears is superior to another.\(^1\)
- High-cost medications for DED are effective compared to vehicle. However, there is insufficient evidence to establish high-cost medications for DED are superior to artificial tears as first-line treatments for DED.
  - Lifitegrast ophthalmic (Xiidra) improved inferior corneal staining score and a measure of patient symptoms in three randomized, phase III trials compared to vehicle. \(^2-4\)
  - Cyclosporine ophthalmic (Restasis) improved patient symptoms and signs of ocular damage when compared to control. \(^5\)
- The American Academy of Ophthalmology Preferred Practice Pattern recommends the use of artificial tears in addition to environmental/lifestyle modifications as first line therapy for the treatment of mild DED. For patients with moderate DED who experience insufficient relief from first-line therapies, the addition of cyclosporine (Restasis) to artificial tears is recommended. Lifitegrast (Xiidra) was not available at the time these guidelines were written.\(^6\)

Dosing
- Lifitegrast ophthalmic (Xiidra) and cyclosporine ophthalmic (Restasis) are dosed twice daily. \(^7\)
Cross References

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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References


Revision History

<table>
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<tr>
<th>Revision Date</th>
<th>Revision Summary</th>
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<tr>
<td>12/16/2016</td>
<td>New policy (effective 1/1/17).</td>
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