Xiidra

Description

Xiidra (lifitegrast ophthalmic solution)

Background
Xiidra ophthalmic solution is used to treat dry eye disease. Xiidra contains lifitegrast ophthalmic solution packaged in sterile, preservative-free single-use vials and is administered every 12 hours. Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. In patients whose tear production is presumed to be suppressed due to ocular inflammation due to dry eye disease, lifitegrast solution increases tear production and is thought to act as a partial immunomodulator (1-2).

Regulatory Status
FDA-approved indication: Xiidra is a lymphocyte function-associated antigen-1 (LFA-1) antagonist indicated for the treatment of the signs and symptoms of dry eye disease (DED) (1).

The safety and efficacy of Xiidra has not been established in pediatric patients below the age of 17 (1).

Related policies
Restasis

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Xiidra may be considered **medically necessary** in patients 17 years of age or older for the treatment of chronic dry eyes and if the conditions indicated below are met.

Xiidra may be considered **investigational** in patients less than 17 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

17 years of age or older

**Diagnosis**

Patient must have the following:

1. Chronic dry eye
   a. **NO** dual therapy with another legend ophthalmic for the treatment of dry eyes (see Appendix 1)

**Prior – Approval Renewal Requirements**

**Age**

17 years of age or older

**Diagnosis**

Patient must have the following:

1. Chronic dry eye
   a. Patient has had an improvement in symptoms
   b. **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**
5.90.23

Section: Prescription Drugs  
Effective Date: April 1, 2019

Subsection: Topical Products  
Original Policy Date: October 7, 2016

Subject: Xiidra  
Page: 3 of 5

Quantity 180 single use vials every 90 days
Duration 12 months

Prior – Approval Renewal Limits

Quantity 180 single use vials every 90 days
Duration 12 months

Rationale

Summary
Xiidra ophthalmic solution is used to treat chronic dry. Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. In patients whose tear production is presumed to be suppressed due to ocular inflammation due to dry eye disease, lifitegrast solution increases tear production and is thought to act as a partial immunomodulator. The safety and efficacy of Xiidra ophthalmic solution have not been established in pediatric patients below the age of 17 (1-2).

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

References

Policy History

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<td>October 2016</td>
<td>New Addition to PA</td>
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<tr>
<td>December 2016</td>
<td>Annual editorial review Removal of decreased tear production from diagnosis and the addition of the word Restasis to the no dual therapy statement per SME</td>
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<td>September 2017</td>
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<td>December 2017</td>
<td>Removal of inadequate response to two lubricating, moisturizing, or anti-inflammatory ophthalmic medications per SME</td>
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March 2019 Annual review and reference update

**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

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<th>Generic Name</th>
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