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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Topical Products	**Original Policy Date:**	October 7, 2016
Subject:	Xiidra	**Page:**	1 of 5

Last Review Date: March 12, 2021

Xiidra

Description

Xiidra (lifitegrast ophthalmic solution)

Background
Xiidra (lifitegrast) ophthalmic solution is used to treat dry eye disease. Xiidra is 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, Xiidra 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 effectiveness of Xiidra in pediatric patients less than 17 years of age have not been established (1).

Related policies
Cyclosporine Ophthalmics, Eysuvis

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 eye or decreased tear production 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 or decreased tear production
   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 or decreased tear production
   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

Quantity 180 single use vials every 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Xiidra (lifitegrast) ophthalmic solution is used to treat chronic dry or decreased tear production. 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, Xiidra increases tear production and is thought to act as a partial immunomodulator. The safety and effectiveness of Xiidra in pediatric patients less than 17 years of age have not been established (1-2).

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

References

1. Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.
2. Dry Eyes Syndrome Preferred Practice Pattern. American Academy of Ophthalmology. September 2018. Accessed on January 30, 2021.

Policy History

Date	Action
October 2016	New Addition to PA
December 2016	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
September 2017	Annual review and reference update
December 2017	Removal of inadequate response to two lubricating, moisturizing, or anti-inflammatory ophthalmic medications per SME
March 2018	Annual review
March 2019	Annual review and reference update
September 2020	Annual editorial review and reference update. Added “or decreased tear production” to diagnosis

March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of Legend Ophthalmic Medications

Generic Name	Brand Name
cyclosporine	Cequa
cyclosporine	Restasis
lifitegrast	Xiidra
loteprednol	Eysuvis