## Drug Monograph

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| Drug/Drug Class: | **Xiidra® (lifitegrast) solution/ Dry Eye Agents** |
| Prepared for: | MO HealthNet |
| Prepared by: | Xerox Heritage, LLC |

☒ **New Criteria** ☐ **Revision of Existing Criteria**

## Executive Summary

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| **Purpose:** | The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use. | |
| **Dosage Forms & Manufacturer:** | Xiidra® is available in 0.2 ml single-use containers that contain 50 mg lifitegrast per 1 ml.<br><br>Manufacturer: Shire US Inc., Lexington, MA 02421 | |
| **Summary of Findings:** | Xiidra® significantly improved eye dryness score in a 100 point visual analog scale by 4.7 to 12.3 points in 3 of 4 studies and inferior fluorescein corneal staining by 0.17 to 0.23 points in 2 of 4 studies in comparison to placebo. | |
| **Status Recommendation:** | ☐ Prior Authorization (PA) Required<br>☐ Clinical Edit | ☒ Open Access<br>☐ PDL |
| **Type of PA Criteria:** | ☐ Increased Risk of ADE<br>☐ Appropriate Indications | ☐ Preferred Agent<br>☒ No PA Required |

## Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payers are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

## Introduction [2]

Dry eye occurs when the eye does not produce tears properly, or when the tears are not of the correct consistency and evaporate too quickly. In addition, inflammation of the surface of the eye may occur along with dry eye. If left untreated, this condition can lead to pain, ulcers, or scars on the cornea, and some loss of vision.

## Dosage Form(s) [1]

Xiidra® is available in 0.2 ml single-use containers that contain 50 mg lifitegrast per 1 ml.

## Manufacturer [1]

Shire US Inc., Lexington, MA 02421

## Indication(s) [1]

Xiidra® is indicated for the treatment of the signs and symptoms of dry eye disease in patients 17 years and older.

## Clinical Efficacy [1,2] (mechanism of action/pharmacology, comparative efficacy)

The exact mechanism of action of lifitegrast is unknown but it has been shown to bind to lymphocyte function-associated antigen-1 (LFA-1) and block its interaction with intercellular adhesion molecule-1 (ICAM-1). Preventing this interaction m ay inhibit T-cell activation and migration, T-cell adhesion to ICAM-1, and secretion of inflammatory cytokines from mononuclear cells.

Pharmacokinetics:

- Pharmacokinetic trials have not been conducted

Treament with Xiidra® compared with placebo significantly improved symptoms of dry eye in 3 of 4 studies and signs of dry eye in 2 of 4 studies.

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| **STUDY DESIGN** | Four randomized, double-masked, placebo-controlled, 12-week clinical trials (n=1181) |
| **INCLUSION CRITERIA** | Patients with signs and symptoms of dry eye disease |

 

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| **EXCLUSION CRITERIA** | Not specified |
| **TREATMENT REGIMEN** | Patients were randomized to receive Xiidra® or placebo twice daily. Artificial tears were not allowed. |
| **RESULTS** | Xiidra® compared with placebo significantly improved eye dryness score (100-point visual analog scale) by 4.7 to 12.3 points in 3 of 4 studies and inferior fluorescein corneal staining (5-point scale from 0=no staining to 4=coalescent) by 0.17 to 0.23 points in 2 of 4 studies. The mean age of patients was 59 years and 76% were female. |
| **SAFETY** | Not specified |

## Contraindications (1)

- None

## Warnings and Precautions (1)

- None

## Adverse Effects (1)

- The most common (5% to 25%) adverse events in clinical trials consisted of instillation site irritation, dysgeusia, and reduced visual acuity.

## Drug Interactions (1)

- None

## Dosage and Administration (1)

The FDA recommended dose is 1 drop instilled into each eye twice daily, approximately 12 hours apart.

## Cost

| GENERIC NAME | BRAND NAME | MANUFACTURER | STRENGTH | Dose | COST*/ MONTH |
|---|---|---|---|---|---|
| Lifitegrast | Xiidra | Shire | 5% solution | 1 drop in each eye twice daily | $426.60 |
| Cyclosporine | Restasis | Allergan | 0.05% emulsion | 1 drop in each eye twice daily | $426.60 |

* Wholesale Acquisition Cost

 

## Conclusion

Xiidra® is the first of a new class of medications called LFA-1 antagonists. It is indicated to treat the signs and symptoms of dry eye disease. In 12-week, placebo-controlled clinical trials, Xiidra® significantly improved eye dryness score in 3 of 4 studies and inferior fluorescein corneal staining in 2 of 4 studies. The cost per month is the same as Restasis®. The most common adverse events include eye irritation, dysgeusia, and decreased visual acuity.

## Recommendation

MO HealthNet Division recommends Open Access status for this product.

## References


1. Product Information: Xiidra™, lifitegrast ophthalmic solution. Shire US Inc, Lexington, MA, 06/2016.
2. Facts about Dry Eye. Retrieved 11/22/2016 from https://nei.nih.gov/health/dryeye/dryeye



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