Pharmacy Policy Bulletin

Title: Lifitegrast (Xiidra)
Policy #: Rx.01.187

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**
The intent of this policy is to communicate the medical necessity criteria for lifitegrast (Xiidra) as provided under the member's prescription drug benefit.

**Description:**
Dry eye disease (also known as keratoconjunctivitis sicca [KCS]) is a multifactorial disease of the tears and ocular surface that can result in ocular discomfort and visual impairment. This condition affects approximately 8% of the population and is more common in women and the elderly. In the majority of patients, the condition is not sight-threatening and is characterized by intermittently blurred vision and troublesome symptoms of irritation that are usually worse at the end of the day. However, reversible conjunctival squamous metaplasia and punctate epithelial erosions of the conjunctiva and cornea develop in many patients who have clinically significant dry eye. The first line of treatment in patients complaining of dry eye includes artificial tears and environmental coping strategies. Cyclosporine ophthalmic emulsion (Restasis) was the first approved prescription drug available for the treatment of dry eye disease. Specifically, it was approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with KCS.

Lifitegrast binds to the integrin lymphocyte function-associated antigen-1 (LFA-1), a cell surface protein found on leukocytes and blocks the interaction of LFA-1 with its cognate ligand intercellular adhesion molecule-1 (ICAM-1). ICAM-1 may be overexpressed in corneal and conjunctival tissues in dry eye disease. LFA-1/ICAM-1 interaction can contribute to the formation of an immunological synapse resulting in T-cell activation and migration to target tissues. In vitro studies demonstrated that lifitegrast may inhibit T-cell adhesion to ICAM-1 in a human T-cell line and may inhibit secretion of inflammatory cytokines in human peripheral blood mononuclear cells. The exact mechanism of action of lifitegrast in dry eye disease is not known. Lifitegrast (Xiidra) is indicated for the treatment of the signs and symptoms of dry eye disease.
Policy:
Lifitegrast (Xiidra) is approved when BOTH of the following criteria are met:

1. Documentation of use for the treatment of the signs and symptoms of dry eye disease
2. Inadequate response or inability to tolerate BOTH of the following:
   a. 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.)
   b. Cyclosporine ophthalmic (Restasis)

Black Box Warning:
N/A

Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:


Applicable Drugs:
Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Xiidra</td>
<td>lifitegrast</td>
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Cross References:
N/A

Policy Version Number: 2.00
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