

Xiidra (lifitegrast)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Dry eye disease, commonly referred to as dry eye syndrome and also known as keratoconjunctivitis sicca (KCS), is a common ocular condition that occurs when the tears are not able to provide adequate lubrication for the eyes. This deficiency manifests through symptoms such as dryness, red eyes, burning and itching eyes, blurred vision, discomfort, and if neglected, more severe visual complications. The underlying causes of DED span a multitude of factors, but predominantly arise from reduced tear production or increased tear evaporation. Risk factors include older age, female sex, environmental conditions, use of certain medications (e.g. anticholinergics, antihistamines), ocular surgery, and systemic inflammatory diseases like Sjogren's syndrome.

Management of KCS or DED typically includes non-pharmacological management (e.g., frequent blinking, reducing air conditioning/heat, humidifier use), and eye lubricants (e.g., polyethylene glycol or polyvinyl alcohol eye drops and gels). In those with persistent symptoms, providers will typically prescribe topical Restasis (cyclosporine ophthalmic emulsion 0.05%), topical Xiidra (lifitegrast), or other alternative therapies. Other options are punctal plugs to conserve tears, autologous serum tears, and procedures like thermal pulsation.

Xiidra (Lifitegrast) is a lymphocyte function-associated antigen-1 (LFA-1) antagonist indicated for the treatment of signs and symptoms of dry eye disease. The exact mechanism of action by which Xiidra (Lifitegrast) works to improve symptoms of DED is unknown, however it is expected to impact the immune reaction that can cause ocular irritation. The LFA-1 is a cell surface protein which is found on leukocytes (white blood cells) in the eye. Xiidra (Lifitegrast) binds with the LFA-1 surface protein to prevent its interaction with the cognate ligand intercellular adhesion molecule-1 (ICAM-1), which is overexpressed in those with DED. By blocking the interaction between LFA-1 and ICAM-1, it reduces the downstream immune reaction that contributes to worsening dry eyes.

Definitions

“Aqueous tear deficiency” refers to reduced production of the aqueous (water) component of tears, leading to dry eye disease.

“Cognate ligand intercellular adhesion molecule-1 (ICAM-1)”

“Dry Eye Disease (DED)/Dry Eye Syndrome” is an ocular condition wherein tears fail to adequately lubricate the eyes, leading to symptoms like blurred vision and discomfort.

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Keratitis sicca" is another term for keratoconjunctivitis sicca.

"Keratoconjunctivitis sicca" is a condition marked by dryness of the conjunctiva (the membrane lining the eyelids and covering the white part of the eye) and the cornea (the clear, front surface of the eye).

"Ocular burning" is a sensation of burning or stinging in the eyes, potentially caused by certain medications or eye conditions.

"Punctal plugs" are small devices inserted into the tear drainage ducts to conserve tears and treat dry eye disease.

"Schirmer's Test" is a standardized test to measure tear production.

"Sjögren's syndrome" is a chronic autoimmune disorder characterized by dryness of the eyes, mouth, and other mucous membranes due to the body's immune system mistakenly attacking its own cells and tissues.

"Tear Break-Up Time Test" is a diagnostic method that measures the time interval before dry patches form on the eye after a blink, providing insights into tear film stability.

"Tear Evaporation" is the natural process of tears evaporating from the eye surface. An increased rate can result in DED.

"Tear Film" is a thin layer of tears that covers the eye, ensuring lubrication, reducing the risk of infections, and keeping the eye smooth for clear vision.

"Tear Production" is the process of producing fluids to keep the eyes moist, which can be diminished in some individuals leading to DED.

"Thermal pulsation" is a procedure that applies heat and pressure to the eyelids to help treat dry eye associated with meibomian gland dysfunction.

"Xerophthalmia" is a dry eye syndrome caused by a deficiency in vitamin A. It can lead to blindness if not managed.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers Xiidra (lifitegrast) medically necessary when ALL of the following criteria are met:

1. The member is 17 years of age or older; *AND*
2. Xiidra (lifitegrast) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
The requested medication is being used within the Plan's Quantity Limit of: 60 ampules every 30 days.
3. The member meets the applicable [Medical Necessity Criteria for Initial Clinical Review](#) or [Subsequent Clinical Review](#) listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Dry Eye Disease

The Plan considers Xiidra (lifitegrast) medically necessary when ALL of the following criteria are met:

4. The member meets the above [General Medical Necessity Criteria](#); *AND*
5. The member meets ONE (1) of the following documented diagnoses:
 - a. Dry eye disease, such as:
 - i. Chronic dry eye disease; *or*
 - ii. Keratitis sicca; *or*
 - iii. Keratoconjunctivitis sicca; *or*
 - iv. Xerophthalmia; *or*
 - v. Any other form of dry eye syndrome; *or*
 - b. Dry eye conditions due to systemic inflammatory diseases, such as:
 - i. Sjögren's Syndrome; *or*
 - ii. Other systemic inflammatory diseases resulting in dry eye conditions (e.g., autoimmune thyroid disease, rheumatoid arthritis); *or*
 - c. Dry eye conditions due to ocular surface diseases, such as:
 - i. Ocular Graft vs. Host Disease; *or*
 - ii. Corneal Transplant Rejection; *or*
 - iii. Other ocular surface diseases resulting in dry eye conditions (e.g., blepharitis, conjunctivitis, herpes simplex keratitis, meibomian gland dysfunction, ocular rosacea).

If the above prior authorization criteria are met, the requested product will be approved for up to 12 months.^[6]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Dry Eye Disease

The Plan considers Xiidra (lifitegrast) medically necessary when ALL of the following criteria are met:

1. The member meets the above applicable [General Medical Necessity Criteria](#) and/or [Initial Clinical Review](#); **AND**
2. Chart documentation indicates EITHER of the following:
 - a. The member has shown a clinical improvement[†] in symptoms since starting the requested medication; *or*
 - b. The member has experienced disease stability[†] since starting the requested medication.

[†]*Note: Clinical improvement may be characterized by reduction in signs and symptoms such as ocular discomfort, burning, or dryness, and/or an increase in tear production as measured by standardized tests such as Schirmer's test or tear break-up time. Disease stability refers to a halt in disease progression, with signs and symptoms remaining consistent and not worsening over time. These should be supported by the medical documentation.*

If the above reauthorization criteria are met, the requested product will be approved for up to 12 months.^[5]

[Experimental / Investigational, unproven](#)^[5]

Xiidra (lifitegrast) for any other use is considered experimental, investigational, or unproven. Additionally, the safety and efficacy of Xiidra (lifitegrast) has not been established in patients under the age of 17 years.

References

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Clinical Guideline Revision / History Information

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