MEDICAL MUTUAL®

Drug Policy

Policy:	Xiidra (lifitegrast ophthalmic solution)	Annual Review Date: 04/18/2024 Last Revised Date: 04/18/2024

OVERVIEW

Xiidra is indicated for the treatment of the signs and symptoms of dry eye disease and has only been studied in patients aged 17 years or older. Xiidra is a lymphocyte function-associated antigen-1 (LFA-1) antagonist. Inflammation of the lacrimal gland and ocular surface has a major role in dry eye disease. Xiidra binds to the integrin 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. The LFA-1/ICAM-1 interaction can contribute to the formation of an immunological synapse resulting in T-cell activation and migration to target tissues. While the exact mechanism of action of Xiidra in dry eye disease is not known, *in vitro* studies demonstrated that Xiidra 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.

POLICY STATEMENT

This policy involves the use of Xiidra. Prior authorization is recommended for pharmacy benefit coverage of Xiidra. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Xiidra as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Xiidra be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xiidra is recommended in those who meet the following criteria:

1. <u>Dry Eye Disease</u>
Criteria. *Patient must meet the following criteria*

A. The patient is 17 years of age or older; AND
B. Xiidra is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND

C. The provider has administered testing for one of the following homeostasis markers with corresponding results (a, b, c, or d):
   a. Schirmer's test (< 5 mm of wetting over 5 minutes), OR
   b. Non-invasive tear breakup time (< 10 s), OR
   c. Osmolarity (≥ 308 mOsm/L in either eye or interocular difference of > 8 mOsm/L), OR
   d. Ocular surface staining (> 5 corneal spots, > 9 conjucntival spots, or lid margin [≥ 2 mm length and ≥ 25% width]); AND

D. If diagnosis is mild dry eye disease, the patient has tried and failed on preservative free artificial tears.

2. Dry Eye Disease, Continuation of Therapy.
Criteria. *Patient must meet the following criteria*

A. The patient is 17 years of age or older; AND
B. The medication is prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist; AND
C. The patient has had a beneficial response to therapy, including reduced eye irritation, dryness, red eyes, or burning).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xiidra has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use with an Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), or Tyrvaya (varenicline nasal solution).** There are no data to support the concomitant use of Xiidra with an ophthalmic cyclosporine product, Miebo, or Tyrvaya.
   Note: Ophthalmic cyclosporine products are Cequa, Restasis, and Vevye.

2. **Management of dry eyes peri-operative elective eye surgery** (e.g. LASIK).

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Xiidra™ ophthalmic solution [prescribing information]. Lexington, MA: Shire; June 2020.
2. Lin MC, Asbell PA, Margolis T, et al. Dry eye disease. Optom Vis Sci. 2015;92(9):922-924.
3. Yagci A, Gurdal C. The role and treatment of inflammation in dry eye disease. Int Ophthalmol. 2014;34(6):1291-1301.
4. Phadatare SP, Momin M, Nighojkar P, et al. A comprehensive review on dry eye disease: diagnosis, medical management, recent developments, and future challenges. 2015. Available at: http://www.hindawi.com/journals/ap/2015/704946/. Accessed on July 1, 2016.
5. American Academy of Opthalmology Cornea/External Diseases Panel. Preferred Practice Pattern® guidelines. Dry eye syndrome. San Francisco, CA: American Academy of Ophthalmology; 2013. Available at: www.aao.org/ppp. Accessed on September 8, 2016.
6. Optometric clinical practice guideline. Care of the patient with ocular surface disorders. © American Optometric Association 2011. Available at: http://www.aoa.org/documents/CPG-10.pdf. Accessed on September 8, 2016.
7. Craig JP, Nelson JD, Azar DT et al. The TFOS Dry Eye Workshop II: Executive Summary. Ocul Surf. 2017 Aug 7. Pii: S1542-0124(17)30214-8.
8. O'dell, LE. (2015, January 12). Using the SPEED questionnaire to identify dry eye. Optometry Times. Retrieved February 15, 2018. Available at: http://optometrytimes.modernmedicine.com/optometrytimes/news/using-speed-questionnaire-identify-dry-eye?page=full
9. Lifitegrast. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 17 January 2018. Accessed on 24 September 2018.