Clinical Policy: Lifitegrast (Xiidra)

Reference Number: PA.CP.PMN.73
Effective Date: 01/18
Last Review Date: 11/16
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Lifitegrast (Xiidra™) is a lymphocyte function-associated antigen-1 (LFA-1) antagonist.

FDA approved indication
- Treatment of the signs and symptoms of dry eye disease.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria**

It is the policy of of Pennsylvania Health and Wellness® that Xiidra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dry Eye Disease (must meet all)**:**
1. Diagnosis of dry eye disease;
2. Failure of 2 artificial tear products containing different active ingredients, each trialed for ≥ 4 weeks unless member experiences clinically significant adverse effects or has contraindication(s) to all artificial tear products;
3. Request does not exceed health plan approved quantity limit.

Approval duration: 6 months

B. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Dry Eye Disease (must meet all)**:**
1. Currently receiving medication via of Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, new dose does not exceed health plan approved quantity limit.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via of Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key

LFA-1: lymphocyte function-associated antigen-1

V. Dosage and Administration

Instill one drop twice daily in each eye (approximately 12 hours apart).

VI. Product Availability

Ophthalmic solution containing lifitegrast 5% (50 mg/mL)

VII. References

1. Xiidra Prescribing Information. Lexington, MA: Shire US Inc.; July 2016. Available at: https://www.xiidra.com. Accessed August 22, 2016.
2. American Academy of Ophthalmology Cornea/External Disease Panel. Preferred practice guidelines. Dry eye syndrome. San Francisco, CA: American Academy of Ophthalmology; 2013. Available at: www.aao.org/ppp. Accessed August 23, 2016.

Reviews, Revisions, and Approvals	Date	Approval Date