Clinical Policy: Lifitegrast (Xiidra)

Reference Number: CP.PMN.73
Effective Date: 11.01.16
Last Review Date: 05.22
Line of Business: HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lifitegrast (Xiidra®) is a lymphocyte function-associated antigen-1 antagonist.

FDA Approved Indication(s)

Xiidra is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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 DED;
2. Age ≥ 17 years;
3. Failure of any non-prescription wetting agent in the form of drops, ointments, or gels, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of at least one ophthalmic anti-inflammatory agent (*see Appendix B for examples*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of generic ophthalmic cyclosporine emulsion 0.05% (generic Restasis®), unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 2 drops per day in each eye (1 box per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Dry Eye Disease (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2 drops per day in each eye (1 box per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 policies – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DED: dry eye disease
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC wetting agents* • Refresh P.M.® (artificial tear ophthalmic ointment) • Systane® Nighttime (white petrolatum-mineral oil ophthalmic ointment) • Nature's Tears® (hypromellose ophthalmic solution 0.4%) • Artificial Tears (polyvinyl alcohol ophthalmic solution 1.4%) • Lacri-Lube® (artificial tears ointment)	Solution/gel: 1-2 drops into the affected eye(s) 2-4 times/day as needed Ointment: Apply small amount (~1/4 inch) to the inside of the lower eyelid 1-4 times/day as needed	Varies
Lotemax®, Alrex® (loteprednol suspension/ gel)	1-2 drops into the conjunctival sac of the affected eye(s) QID	Varies
dexamethasone solution/suspension (Maxidex®)	1-2 drops into conjunctival sac every	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	hour during the day and every other hour during the night; gradually reduce dose to 1 drop every 4 hours, then to TID-QID	
fluorometholone ointment/suspension (FML®, FML® Forte®, FML® Liquifilm™, Flarex®)	Ointment (FML): Apply small amount (~1/2 inch ribbon) to conjunctival sac 1-3 times daily Suspension (Flarex): 1-2 drops into conjunctival sac QID FML, FML Forte: 1 drop into conjunctival sac BID-QID	Varies
prednisolone (Omnipred®, Pred Forte®, Pred Mild®)	1-2 drops in the affected eye(s) BID-QID	Varies
cyclosporine (Restasis®)	1 drop OU BID	2 drops/eye/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Available over-the-counter in a number of preparations. This list is not all-inclusive*

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DED	Instill 1 drop BID in each eye (~12 hours apart)	2 drops/eye/day

VI. Product Availability

Ophthalmic solution containing lifitegrast 5% (50 mg/mL): 0.2 mL containers (60 or 5 single-use containers/box)

VII. References

1. Xiidra Prescribing Information. Lexington, MA: Shire US, Inc.; June 2020. Available at: https://www.xiidra.com. Accessed December 1, 2021.
2. American Academy of Ophthalmology Cornea/External Disease Committee. Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. Chicago, IL: American Academy of

Ophthalmology; November 2018. Available at: https://www.aaojournal.org/article/S0161-6420(18)32650-2/fulltext#seccestitle330. Accessed December 1, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed December 1, 2021..

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: no significant changes; initial approval duration increased to 12 months; references reviewed and updated.	07.03.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.24.19	11.19
Added HIM line of business.	02.13.20	
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.21.20	11.20
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	07.16.21	11.21
Added requirement for topical anti-inflammatory agents; reduced the number of wetting agents required from 2 to 1; removed duration of trial.	12.01.21	02.22
Per March SDC added redirection to generic Restasis.	03.22.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.