Clinical Policy Title:	lifitegrast
Policy Number:	RxA.315
Drug(s) Applied:	Xiidra®
Original Policy Date:	05/21/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

lifitegrast (Xiidra®) is a lymphocyte function-associated antigen-1 antagonist.
Xiidra is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

Dosing Information

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

Dosage Forms

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

Clinical Policy

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

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 an ophthalmic corticosteroid therapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Dry Eye Disease (must meet all):

1. Currently receiving medication via Rx Advance 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DED: Dry eye disease
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC wetting agents	1-2 drops in affected eye(s) BID-QID	Not applicable
Restasis® (cyclosporine)	1 drop OU BID	2 drops/eye/day
Lotemax®, Alrex® (loteprednol suspension/ gel)	1-2 drops into the conjunctival sac of the affected eye(s) QID	Not applicable
dexamethasone solution/suspension (Maxidex®)	1-2 drops into conjunctival sac every hour during the day and every other hour during the night; gradually reduce dose to 1 drop every 4 hours, then to TID-QID	Not applicable
fluorometholone ointment/suspension (FML®, FML® Forte®, FML® LiquifilmTM, 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	Not applicable

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.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- None

References

1. Xiidra Prescibing Information. Lexington, MA: Shire US, Inc.; December 2017. Available at: https://www.xiidra.com. Accessed May 4, 2020.
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: www.aao.org/ppp. Accessed May 4, 2020.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 4, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Updated References	05/04/2020	05/21/2020
1. Updated the Initial Approval Criteria I.A.4 from "failure of Restasis or an ophthalmic corticosteroid therapy…" to "failure of an ophthalmic corticosteroid therapy" **and** "failure of Restasis". 2. Updated approval durations for both Initial Approval and Continued Therapy from "length of benefit" to "12 months".	12/03/2020	12/07/2020