

## Ophthalmic Immunomodulators –

### lifitegrast 5% ophthalmic solution (Xiidra™)

# WA.PHAR.58 Ophthalmic Immunomodulators- Lifitegrast 5% Ophthalmic Solution

### Effective: October 1, 2018

#### **Medical necessity**

Drug	Medical Necessity
lifitegrast 5% ophthalmic solution (Xiidra™)	Xiidra <sup>™</sup> may be considered medically necessary when prescribed for a dry eye disease

#### **Clinical policy:**

Clinical Criteria	
Initial Authorization Criteria	<ol> <li>Diagnosis of moderate to severe chronic dry eye disease (DED)</li> <li>Documentation is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods:         <ul> <li>a. Tear break-up time (less than 10 seconds)</li> <li>b. Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes</li> <li>c. Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes)</li> <li>d. Fluorescein clearance test/tear function index</li> <li>e. Tear osmolarity (indicating tear film instability)</li> <li>f. Tear lactoferrin concentrations in the lacrimal gland (decreased)</li> </ul> </li> <li>History of failure, contraindication or clinically significant intolerance to cyclosporine 0.05% ophthalmic emulsion (RESTASIS®) for at least 28-days</li> <li>Greater than or equal to (≥) 17 years of age</li> <li>Not used concomitantly with cyclosporine 0.05% ophthalmic emulsion (RESTASIS®)</li> <li>Dose does not exceed 2 drops per day in each eye</li> <li>Prescribed by or in consultation with a specialist in eye care or rheumatology</li> </ol>
Reauthorization Criteria	1. Documentation of clinically significant improvement



	<ol> <li>Continues to not use concomitantly with cyclosporine 0.05% ophthalmic emulsion (RESTASIS®)</li> <li>Dose does not exceed 2 drops per day in each eye</li> <li>Approve for 6 months</li> </ol>
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#### Dosage and quantity limits

Drug Name	Dose and Quantity Limits
lifitegrast 5% ophthalmic solution (XIIDRA <sup>™</sup> )	One drop in each eye twice daily; #60 single-use vials per 30-days

#### References

- 1. Product Information: XIIDRA<sup>®</sup> topical ophthalmic solution, lifitegrast 5% topical ophthalmic solution. Shire US Inc (per FDA), Lexington, MA, 2017.
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- 4. Baiza-Durán L, Medrano-Palafox J, Hernández-Quintela E, et al. A comparative clinical trial of the efficacy of two different aqueous solutions of cyclosporine for the treatment of moderate-to-severe dry eye syndrome. *Br J Ophthalmol.* 2010 Oct;94(10):1312-5.
- 5. Brown MM, Brown GC, Brown HC, et al. Value-based medicine, comparative effectiveness, and costeffectiveness analysis of topical cyclosporine for the treatment of dry eye syndrome. *Arch Ophthalmol*. 2009 Feb;127(2):146-52.
- 6. Mah F., et al. PERSIST: Physician's Evaluation of Restasis(<sup>®</sup>) Satisfaction in Second Trial of topical cyclosporine ophthalmic emulsion 0.05% for dry eye: a retrospective review. *Clin Ophthalmol.* 2012;6:1971-6.
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- 9. Pucci N, Novembre E, Cianferoni A, et al. Efficacy and safety of cyclosporine eyedrops in vernal keratoconjunctivitis. *Ann Allergy Asthma Immunol*. 2002 Sep;89(3):298-303.
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- 12. Semba CP, Torkildsen GL, Lonsdale JD, et al. A phase 2 randomized, double-masked, placebocontrolled study of novel integrin antagonist (SAR 1118) for the treatment of dry eye. Am J Opthalmol. 2012;153(6):1050-60.
- 13. Sheppard JD, Torkildsen GL, Lonsdale JD, et al. Lifitegrast ophthalmic solution 5.0% for treatment of DED: results of the OPUS-1 phase 3 study. Ophthalmology. 2014;121(2):475-83.
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- 15. Xiidra (lifitegrast) [package insert]. Lexington, MA: Shire US Inc.; July 2016.