

# Ophthalmic Immunomodulators – lifitegrast 5% ophthalmic solution (Xiidra™)

Medical policy no. 86.73.40-1

Effective: October 1, 2018

## Medical necessity

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

## Clinical policy:

| Clinical Criteria                     |   |
|---------------------------------------|---|
| <b>Initial Authorization Criteria</b> | <ol style="list-style-type: none"> <li>1. Diagnosis of moderate to severe chronic dry eye disease (DED)</li> <li>2. Documentation is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods:               <ol style="list-style-type: none"> <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> </ol> </li> <li>3. History of failure, contraindication or clinically significant intolerance to cyclosporine 0.05% ophthalmic emulsion (RESTASIS®) for at least 28-days</li> <li>4. Greater than or equal to (<math>\geq</math>) 17 years of age</li> <li>5. Not used concomitantly with cyclosporine 0.05% ophthalmic emulsion (RESTASIS®)</li> <li>6. Dose does not exceed 2 drops per day in each eye</li> <li>7. Prescribed by or in consultation with a specialist in eye care or rheumatology</li> </ol> <p><b>Approve for 6 months</b></p> |
| <b>Reauthorization Criteria</b>       | <ol style="list-style-type: none"> <li>1. Documentation of clinically significant improvement</li> <li>2. Continues to not use concomitantly with cyclosporine 0.05% ophthalmic emulsion (RESTASIS®)</li> <li>3. Dose does not exceed 2 drops per day in each eye</li> </ol>  |

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|  | Approve for 6 months |
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## Dosage and quantity limits

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

## References

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6. Mah F., et al. PERSIST: Physician's Evaluation of Restasis® 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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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 Ophthalmol*. 2012;153(6):1050-60.
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15. Xiidra (lifitegrast) [package insert]. Lexington, MA: Shire US Inc.; July 2016.