

Pharmacy Policy

Restasis[®], Xiidra[™]

Policy Number: 9.902

Version Number: 2.0

Version Effective Date: 3/1/2022

Product Applicability All Plan⁺ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Restasis[®] (cyclosporine)
- Xiidra[™] (lifitegrast)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Restasis: Member is not currently on topical anti-inflammatory drugs
Required Medical Information	<p>Restasis[®]</p> <ol style="list-style-type: none"> 1. A confirmed diagnosis of <ol style="list-style-type: none"> a) Moderate to severe chronic ocular inflammation associated with keratoconjunctivitis sicca; OR b) A high risk for corneal transplant rejection; AND 2. An inadequate response or intolerance to at least two 30 day trials of at least two different

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	artificial tears or ocular lubricant products. Xiidra™ 1. A confirmed diagnosis of moderate to severe dry eye disease; AND 2. An inadequate response or intolerance to at least two 30 day trials of at least two different artificial tears or ocular lubricant products.
Age Restriction	Restasis: 16 years and older Xiidra: 17 years and older
Prescriber Restriction	Prescribed by or in consultation with an ophthalmologist, optometrist, or rheumatologist;
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. A diagnosis of dry eye disease, moderate-severe keratoconjunctivitis sicca or corneal transplant rejection requiring continued treatment; AND 2. There has been a clinical response to therapy without adverse events.

Applicable Coding:

None

Clinical Background Information and References

1. Restasis® [package insert]. Irvine (CA): Allergan, Inc.; Accessed Sept 2021.
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6. Tabbara KF. Pharmacologic strategies in the prevention and treatment of corneal transplant rejection [abstract]. Int Ophthalmol. 2008;28:223-232.
7. Price MO, Price FW Jr. Efficacy of topical cyclosporine 0.05% for prevention of cornea transplant rejection episodes [abstract]. Ophthalmology. 2006 Oct;113(10):1785-90.
8. Unal M, Yücel I. Evaluation of topical ciclosporin 0.05% for prevention of rejection in high-risk corneal grafts [abstract]. Br J Ophthalmol. 2008 Oct;92(10):1411-4.
9. Poon A, Constantinou M, Lamoureux E, Taylor HR. Topical 2yclosporine A in the treatment of acute graft rejection: a randomized-controlled trial [abstract]. Clin Experiment Ophthalmol. 2008 Jul;36(5)L415-21.
10. American Academy of Ophthalmology Corneal/External Disease Panel. Cornea/External Disease Summary Benchmarks – 2020; Summary Benchmarks For Preferred Practice Pattern®, Dry Eye Syndrome. American Academy of Ophthalmology; 2020. Oct 2020; 11-12.
11. Wilson SE, Perry HD. Long-term resolution of chronic dry eye symptoms and signs after topical cyclosporine treatment. Ophthalmology 2007; 114(1):76-9.
12. Perry HD, Solomon R, et al. Evaluation of Topical Cyclosporine for the Treatment of Dry Eye Disease. Arch Ophthalmol. 2008;126(8):1046-1050

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14. Utine CA, et al. Clinical Review: Topical Ophthalmic Use of Cyclosporin A. *Ocular Immunology & Inflammation*. 18(5), 352-361, 2010.
15. Xiidra (lifitegrast) [prescribing information]. Lexington, MA: Shire US Inc.; Accessed Sept 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.022 Restasis and Xiidra Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	No policy changes recommended	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

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The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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