

Pharmacy Policy

Restasis[®], Xiidra[™]

Policy Number: 9.902

Revision Number: R1

Version Effective Date: 1/1/2021

<p>Product Applicability <input type="checkbox"/> All Plan⁺ Products</p>	
<p>Well Sense Health Plan</p> <p><input checked="" type="checkbox"/> New Hampshire Medicaid</p> <p><input type="checkbox"/> _____</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p> <p><input type="checkbox"/> _____</p>

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 one of the following: <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 intolerance or inadequate response to at least a 30 day trial each of two different artificial tears or ocular lubricant products.

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	Xiidra™ 1. A confirmed diagnosis of moderate to severe dry eye disease; AND 2. An intolerance or inadequate response to at least a 30 day trial each of 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:

Clinical Background Information and References

1. Restasis® [package insert]. Irvine (CA): Allergan, Inc.; 2013.
2. Fox R, Creamer P. Treatment of Sjögren's syndrome. UptoDate,® accessed 2009 Oct; available from <http://uptodate.com>
3. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Micromedex; 2009 [accessed 2009 Oct]. Available from: <http://www.thomsonhc.com/>.
4. Gilboe IM, Kvien TK, Uhlig T, Husby G. Sicca symptoms and secondary Sjögren's syndrome in systemic lupus erythematosus: comparison with rheumatoid arthritis and correlation with disease variables. *Ann Rheum Dis*. 2001;60:1103-1109.
5. Claes K, Kestelyn P. Ocular manifestations of graft versus host disease following bone marrow transplantation. *Bull Soc belge Ophtalmol*. 2000;277:21-26.
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. Preferred Practice Pattern Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2008. Available at: <http://www.aao.org/ppp>.
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
13. Panda A. et al. Cornea graft rejection. *Surv Ophthalmol* 2007 Jul-Aug;52(4):375-96

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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.; June 2016.

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

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	P&T Committee- discontinued policy 9.022 and created a separate policy for NH	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

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.

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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.

[†] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.