

Pharmacy Policy

Xiaflex

Policy Number: 9.911

Revision Number: R1

Version Effective Date: 1/1/2021

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:

- **Xiaflex (collagenase clostridium histolyticum)**

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	None
Required Medical Information	<ol style="list-style-type: none"> 1. A diagnosis of Dupuytren’s contracture with palpable cords that significantly impairs daily function of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more (excluding the thumb); AND 2. Must not have had surgery on the primary joint within the past 90 days <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> 1. A diagnosis of moderate to severe Peyronie’s Disease (PD) with a palpable plaque and curvature of greater than 30 degrees; AND

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	2. Symptoms have persisted for greater than 12 months; AND 3. An inadequate response, contraindication or intolerance to a trial (6 months or greater) of appropriate alternative treatments such as pentoxifylline or intralesional verapamil.
Age Restriction	18 years of age and older
Prescriber Restriction	None
Coverage Duration	Dupuytren's contracture: 3 months Peyronie's disease: 6 months
Other criteria	None

Clinical Background Information and References

1. Product Information. Xiaflex™ (collagenase clostridium histolyticum). Auxilium Pharmaceuticals, Inc. Malvern, PA 19355. July 2015.
2. Eric Brodsky, MD. FDA Perspective- Xiaflex™ for Advanced Dupuytren's Disease. Available at http://www.dupuytrenfoundation.org/DupPDFs/2009_FDA.pdf Accessed April 14, 2010
3. Rohit A and Blazar PE. Dupuytren's Contracture. Up to Date online. Accessed Feb, 2018.
4. **Ghazi M. Rayan, MD.** Dupuytren Disease: Anatomy, Pathology, Presentation, and Treatment. *The Journal of Bone and Joint Surgery (American)*. 2007;89:189-198. Accessed April 14, 2010.
5. Lawrence C. Hurst, M.D., etc. Injectable Collagenase Clostridium Histolyticum for Dupuytren's Contracture. *The New England Journal of Medicine*. 2009; Volume 361:968-979
6. Brant WO et al. Peyronie's disease: Diagnosis and Medical Management. UpToDate. Available at www.uptodate.org. Accessed February, 2018
7. Sherer BA et al. 2013-2014 Updates in Peyronie's Disease Management. *Curr Urol Rep*. 2014 Dec;15(12):459.

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	9.169 Xiaflex Policy retired, new policy created	1/1/2021	P&T Committee, NH DHHS

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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.

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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