

Policy Name:	Xiaflex (collagenase clostridium histolyticum)	Policy #:	2251P
---------------------	---	------------------	--------------

Purpose of the Policy

The purpose of this policy is to define the criteria for the coverage of Xiaflex (collagenase clostridium histolyticum).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Xiaflex (collagenase clostridium histolyticum) under the specialty medical benefit when the following criteria have been met.

Criteria

- 1. Coverage criteria for use in Dupuytren's contracture with a palpable cord**
 - 1.1 Documented contracture (muscle tightening) of a joint within the knuckles that is greater than or equal to 30 degrees
 - 1.2 Prescribed by an orthopedic or hand surgeon
- 2. Coverage criteria for use in Peyronie's Disease**
 - 2.1 Documented presence of a palpable plaque and penile curvature greater than or equal to 30 degrees before start of therapy
 - 2.2 Prescribed by a urologist (urinary tract doctor)
- 3. Exclusion Criteria**
 - 3.1 Xiaflex for the treatment of moderate to severe cellulite in adult females is not covered by Health Alliance. This indication is considered cosmetic in nature and not deemed medically necessary.
- 4. Approval Period**
 - 4.1 Dupuytren's contracture: up to 2 injections per hand allowed within 4 week regimen; may repeat twice every 4 weeks, approve a maximum of 3 visits in 6 months
 - 4.2 Peyronie Disease: up to 2 injections within 6 week regimen; may repeat up to 2 injections every 6 weeks; approve a maximum of 8 visits in 6 months

HCPCS Codes

J0775	Injection, collagenase clostridium histolyticum, 0.01mg
-------	---

References

1. Xiaflex (collagenase clostridium histolyticum) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; July 2023.
2. Coleman S, Gilpin D, Kaplan FT, et al. Efficacy and safety of concurrent collagenase clostridium histolyticum injections for multiple Dupuytren contractures. *J Hand Surg Am* 2014; 39:57.
3. Peimer CA, Blazar P, Coleman S, et al. Dupuytren Contracture Recurrence Following Treatment With Collagenase Clostridium histolyticum (CORDLESS [Collagenase Option for Reduction of Dupuytren Long-Term Evaluation of Safety Study]): 5-Year Data. *J Hand Surg Am* 2015; 40:1597.
4. Trojian TH, Chu SM. Dupuytren's disease: diagnosis and treatment. *Am Fam Physician* 2007; 76:86.
5. Gelbard M, Goldstein I, Hellstrom WJ, et al. Clinical efficacy, safety and tolerability of collagenase clostridium histolyticum for the treatment of peyronie disease in 2 large double-blind, randomized, placebo controlled phase 3 studies. *J Urol* 2013; 190:199.
6. Nguyen HMT, Yousif A, Chung A, et al. Safety and Efficacy of Collagenase Clostridium histolyticum in the Treatment of Acute Phase Peyronie's Disease: A Multi-institutional Analysis. *Urology* 2020; 145:147.
7. Russo GI, Milenkovic U, Hellstrom W, et al. Clinical Efficacy of Injection and Mechanical Therapy for Peyronie's Disease: A Systematic Review of the Literature. *Eur Urol* 2018; 74:767.

Created Date: 06/04/14

Effective Date: 06/04/14

Posted to Website: 01/01/22

Revision Date: 06/05/24

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.