



Pharmacy Drug Policy & Procedure

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

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DISCLAIMER

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