Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Xiaflex® (collagenase clostridium histolyticum)

Effective: September 9, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications

Xiaflex (collagenase clostridium histolyticum) is a combination of bacterial collagenases indicated for the treatment of:

- **Dupuytren's contracture**
  Adult patients with Dupuytren's contracture with a palpable cord
- **Peyronie's disease**
  Adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xiaflex for Members when **ALL** of the following criteria are met:

Dupuytren's contracture

1. Documented diagnosis of Dupuytren's contracture

AND

2. Documentation of a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint prior to initiating Xiaflex therapy

AND

3. Prescribed by or in consultation with a hand surgeon, plastic surgeon, orthopedic surgeon, or rheumatologist

AND

4. Documentation the contracture is at least 20 degrees prior to initiating Xiaflex therapy

AND

5. Documentation that the flexion deformity results in functional limitations

AND

6. Patient is at least 18 years of age or older

AND

7. Documentation the patient will receive a maximum of three (3) injections per cord at an interval of four (4) weeks

Peyronie's disease

1. Documented diagnosis of Peyronie's disease

AND

2. Documentation of **both** of the following:
   a. Palpable plaque
   b. Curvature deformity is at least 30 degrees prior to initiating Xiaflex therapy

AND

3. Prescribed by or in consultation with a urologist

AND

4. Patient is at least 18 years of age or older

AND

5. Documentation the patient has intact erectile function (with or without medication)

AND

6. Documentation the patient will receive a maximum of one treatment course with a maximum of 8 injections total, including any injections the patient has received for any previous treatment

Limitations

- For Peyronie's disease, the duration of approval for Xiaflex is 12 months.
- The continued use of Xiaflex beyond one treatment course (4 treatment cycles; 8 injection procedures and 4 modeling procedures) in the patient's lifetime is unproven and not medically necessary.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg

References

1. Azzopardi E, Boyce DE. Clostridium histolyticum collagenase in the treatment of Dupuytren's contracture. Br J Hosp Med (Lond). 2012 Aug;73(8):432-6.
2. Bainbridge C, Gerber RA, Szczypa PP et al. Efficacy of collagenase in patients who did and did not have previous hand surgery for Dupuytren's contracture. J Plast Surg Hand Surg. 2012 Sep;46(3- 4):177-83. Epub 2012 Jun 7.
3. Food and Drug Administration briefing document. Arthritis Advisory Committee Meeting: Collagenase clostridium histolyticum (Xiaflex) for the treatment of advanced Dupuytren's disease; 16 September 2009.
4. Gelbard M, Goldstein I, Hellstrom WJ, et al. Clinical efficacy, safety and tolerability of collagenase clostridium histolyticum for the treatment of Peyronie's disease in 2 large double-blind, randomized, placebo controlled phase 3 studies. J Urol. 2013 Jul; 190(1):199-207.
5. Gelbard M, Hellstrom WJ, McMahon CG, et al. Baseline Characteristics from an Ongoing Phase 3 Study of Collagenase Clostridium Histolyticum in Patients with Peyronie's Disease. J Sex Med. 2013 Sep 24.
6. Halal AA, Geavlete P, Ceban E. Pharmacological therapy in patients diagnosed with Peyronie's disease. J Med Life. 2012 Jun 12; 5(2):192-5.
7. Hurst LC, Badalamente MA, Hentz VR et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med. 2009; 361:968-79.
8. Hurst LC, Badalamente MA, Wang ED. Injectable clostridial collagenase: striving toward non- operative treatment options for fibroproliferative disorders. Available at aaos.org/research/committee/research/Kappa/KD2009_Hurst.pdf Accessed 16 August 2010.
9. Levine LA, Cuzin B, Mark S, et al. Clinical safety and effectiveness of collagenase clostridium histolyticum injection in patients with Peyronie's disease: a phase 3 open-label study. J Sex Med. 2015 Jan;12(1):248-58.
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11. Peimer CA, Blazar P, Coleman S, Kaplan FT, Smith T, Lindau T. Dupuytren's Contracture Recurrence Following Treatment With Collagenase Clostridium histolyticum (CORDLESS [Collagenase Option for Reduction of Dupuytren's

Long-Term Evaluation of Safety Study]): 5-Year Data. https://www.uptodate.com/contents/dupuytrens-contracture/abstract/29#:~:text=J%20Hand%20Surg%20Am.%202015%20Aug%3B40(8)%3A1597%2D605.%C2%A0
12. Rozen WM, Edirisinghe Y, Crock J. Late Complications of Clinical Clostridium Histolyticum Collagenase Use in Dupuytren's Disease. PLoS One. 2012;7(8):e43406.
13. Trojian TH and Chu SM. Dupuytren's disease: diagnosis and treatment. Am Fam Physician. 2007; 76:86-9.
14. Witthaut J, Bushmakin AG, Gerber RA, et al. Determining clinically important changes in range of motion in patients with Dupuytren's Contracture: secondary analysis of the randomized, double- blind, placebo-controlled CORD I study. Clin Drug Investig. 2011 Nov 1;31(11):791-8.
15. Xiaflex (collagenase clostridium histolyticum) [package insert]. Malvern, PA: Auxilium Pharmaceuticals, Inc.; July 2023.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Removed the Limitation For the diagnosis of Dupuytren's contracture: Authorization will be limited to metacarpophalangeal joint contractures or proximal interphalangeal joint contractures and Authorization will be limited per joint as follows: One injection per month for a maximum of three injections per cord. For Dupuytren's contracture, added patient age, consolidated contracture degree criterion, separated out diagnosis criterion, added "Documentation the patient will receive a maximum of three (3) injections per cord at an interval of four (4) weeks." Removed the Limitation For the diagnosis of Peyronie's disease Initial authorization will be limited to one treatment cycle consisting of two Xiaflex injection procedures and one penile modeling procedure AND For each plaque causing the curvature deformity, up to four treatment cycles may be approved (maximum of eight injection procedures and four modeling procedures). Removed Initial approval of Xiaflex for Peyronie's disease will be authorized for 5 months. Reauthorization of Xiaflex will be authorized for 1 month. For the diagnosis of Peyronie's disease. Initial authorization will be limited to one treatment cycle consisting of two Xiaflex injection procedures and one penile modeling procedure. For each plaque causing the curvature deformity, up to four treatment cycles may be approved (maximum of eight injection procedures and four modeling procedures. For Peyronie's disease, separated out diagnosis and palpable cored and contracture requirements, added dosing requirements into coverage criteria, and updated duration of approval to 12 months (effective 2/1/2024).
- September 10, 2024: Removed Reauthorization Criteria for Peyronie's disease. Added the Limitation "The continued use of Xiaflex beyond one treatment course (4 treatment cycles; 8 injection procedures and 4 modeling procedures) in the patient's lifetime is unproven and not medically necessary." (effective 1/1/2025).
- September 2024: Administrative Update: Rebranded from Tufts Health Unify to Tufts Health One Care.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- September 9, 2025: No changes.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to

eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.