TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Xiaflex® (collagenase clostridium histolyticum)

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED /RX	Department to Review	PRECERT /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products
☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products
☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

All plans except Tufts Health Public Plans:
Precert: 617.972.9409

Tufts Health Public Plans:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-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

COVERAGE GUIDELINES

The plan may authorize coverage of Xiaflex (collagenase clostridium histolyticum) for Members when all of the following criteria are met:

Dupuytren's contracture

1. Documented diagnosis of Dupuytren's contracture with a palpable cord
   AND
2. A positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top)
   AND
3. Documented contracture of at least 40 degrees flexion for a metacarpophalangeal joint contracture or at least 20 degrees flexion for a proximal interphalangeal joint contracture
   AND
4. Documentation that the flexion deformity results in functional limitations

Note: Injections should be administered at no less than four week intervals.

Peyronie's disease

1. Documented diagnosis of Peyronie's disease with a palpable plaque
   AND
2. Curvature deformity is at least 30 degrees at the start of therapy
   AND
3. The prescribing physician is a urologist or otherwise experienced in the treatment of male urological diseases
   AND
4. Documentation that Peyronie's disease symptoms have been present for at least 12 months
   AND
5. The Member is at least 18 years of age

Note: Injections should be administered at no less than six week intervals.

LIMITATIONS

- For the diagnosis of Dupuytren's contracture:
  - Authorization will be limited to metacarpophalangeal joint contractures or proximal interphalangeal joint contractures.
  - Authorization will be limited per joint as follows: One injection per month for a maximum of three injections per cord.
- 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.
  - Subsequent authorization(s) for additional treatment cycles may be given if the curvature deformity is more than 15 degrees after the first, second or third treatment cycle, or if the prescribing healthcare provider determines that further treatment is clinically indicated.
  - For each plaque causing the curvature deformity, up to four treatment cycles may be approved (maximum of eight injection procedures and four modeling procedures).

CODES

The following HCPCS/CPT code(s) are:

Code	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 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.
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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.
10. Lipshultz LI, Goldstein I, Seftel AD, et al. Clinical efficacy of collagenase Clostridium histolyticum in the treatment of Peyronie's disease by subgroup: results from two large, double-blind, randomized, placebo-controlled, phase III studies. *BJU Int*. 2015 Oct;116(4):650-6.
11. Rozen WM, Edirisinghe Y, Crock J. Late Complications of Clinical Clostridium Histolyticum Collagenase Use in Dupuytren's Disease. *PLoS One.* 2012;7(8):e43406.
12. Trojian TH and Chu SM. Dupuytren's disease: diagnosis and treatment. *Am Fam Physician.* 2007; 76:86-9.
13. 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.
14. Xiaflex (collagenase clostridium histolyticum) [package insert]. Malvern, PA: Auxilium Pharmaceuticals, Inc.; June 2018.

APPROVAL HISTORY

September 14, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2011: Administrative Update: Removed temporary code C9266 and replaced with code J0775.
2. September 13, 2011: No changes.
3. September 11, 2012: No changes.
4. September 10, 2013: No changes.
5. February 11, 2014: Added coverage guidelines for the diagnosis of Peyronie's disease.
6. January 13, 2015: No changes.
7. January 1, 2016: Administrative change to rebranded template.
8. February 9, 2016: No changes
9. April 12, 2016: Effective 10/01/2016, Medical Necessity Guideline applies to Tufts Health Together.
10. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
11. March 13, 2018: No changes.
12. February 12, 2019: No changes.
13. November 10, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.