Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: September 15, 2026

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

Public Plans Products

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

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 – 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 (collagenase clostridium histolyticum) 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

None

References

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Approval And Revision History

September 10, 2024: Reviewed by the Pharmacy & Therapeutics Committee (eff 1/1/25).

- September 9, 2025: No changes.
- September 15, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

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.