Mass General Brigham
Health Plan

Xiaflex (collagenase clostridium histolyticum)
Effective 09/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

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

1. Adult patients with Dupuytren's contracture with a palpable cord
2. 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

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Approval will be granted when all of the following diagnosis-specific criteria are met:

<u>Dupuytren's Contracture</u>

1. Diagnosis of Dupuytren's contracture with a palpable cord
2. Member is 18 years of age or older
3. Finger flexion contracture with palpable cord in metacarpophalangeal joint or a proximal interphalangeal joint prior to therapy initiation
4. Contracture is at least 20 degrees prior to therapy initiation

<u>Peyronie's Disease</u>

1. Diagnosis of Peyronie's disease with a palpable plaque
2. Member is 18 years of age or older
3. Peyronie's disease symptoms have been present for at least 12 months
4. Curvature deformity is at least 30 degrees at the start of therapy
5. Prescribed by or in consultation with one of the following:
    a. Urologist
    b. Specialist in the treatment of male urological diseases

Continuation of Therapy

Peyronie's disease:

Requests for reauthorization for Peyronie's disease will be granted when all of the following criteria are met:

1. Curvature deformity is greater than 15 degrees after the first, second or third treatment cycle.
2. Maximum of four treatment cycles or a total of eight injection procedures and 4 penile modeling procedures.

Limitations

1. The following quantity limits apply:

Condition	Quantity Limitations
Dupuytren's Contracture	Approvals will be granted for 3 months Up to 3 injections per cord, 2 cords per hand
Peyronie's Disease	Approvals will be granted for 6 months <u>Initial Approval</u> Up to one treatment cycle of two Xiaflex injection procedures and one penile modeling procedure. <u>Reauthorization</u> Maximum of four treatment cycles or a total of eight injection procedures and 4 penile modeling procedures.

References

1. Xiaflex (collagenase clostridium histolyticum) [prescribing information] Rochester, MI: Endo USA; March 2026.

Review History

11/28/2016 – Reviewed
11/27/2017 – Reviewed
03/18/2020 – Reviewed and Updated P&T Mtg
07/22/2020 – reviewed and Updated July P&T Mtg; updated Approval Limitation to include duration of approval. Effective 10/01/20.
05/14/2025 – Reviewed and updated at May P&T. Added language for members who are new to the plan. Updated criteria for Dupuytren's contracture to require: diagnosis, member is 18 years of age or older, finger flexion contracture with palpable cord in metacarpophalangeal or proximal interphalangeal joint prior to starting therapy, and contracture is at least 20 degrees prior to starting therapy. Effective 08/01/2025.
05/13/2026 – Reviewed and updated at May P&T. Updated criteria for Peyronie's disease to remove trial and failure with initial agent (e.g., pentoxifylline, verapamil). Updated language for members who are new to the plan. Effective 09/01/2026.