

Collagenase clostridium histolyticum (Xiaflex®)

Place of Service

Office Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration

HCPCS: J0775 per 0.01 mg

Condition listed in policy (see criteria for details)

- [Dupuytren's contracture](#)
- [Peyronie's disease](#)

AHFS therapeutic class: Enzymes

Mechanism of action: Collagenases are proteinases that hydrolyze collagen in its native triple helical conformation under physiological conditions resulting in lysis of collagen deposits.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Xiaflex® (collagenase clostridium histolyticum) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Dupuytren's contracture

1. Has at least one finger (not thumb) flexion contracture with a palpable cord of 20° to 100° in the metacarpophalangeal joint (MP), or 20° to 80° in a proximal interphalangeal (PIP) joint

Covered Doses

One injection of 0.58 mg per cord per session (Up to 3 sessions can be given per cord with at least 4-weeks in between a session).

Maximum of up to 2 cords in the same hand per treatment visit. Each cord requested must meet the coverage criteria listed in the bullets above.

Coverage Period

Cover for 3 months. Reauthorization based upon continued response to treatment

ICD-10:

M72.0

Peyronie's Disease

1. Prescribed by or in consultation with a urologist

Covered Doses

Up to 2 injections of 0.58 mg Xiaflex injected into the target plaque, administered 1 to 3 days apart. For each plaque causing the curvature deformity, up to four treatment cycles may be administered. Each treatment cycle consists of two injections given at six-week intervals for up to four cycles (maximum of 8 injections per plaque for the entire treatment course)

Coverage Period

Up to four cycles at six-week intervals (one treatment course per plaque)

ICD-10:

N48.6

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Xiaflex® (collagenase clostridium histolyticum) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Cellulite
- Flexor tendon adhesions of the hand
- Adhesive capsulitis (frozen shoulder)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

0.9 mg (Single-use glass vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease American Urological Association Guideline. Updated April 2015. Available at: <https://www.auanet.org/documents/education/clinical-guidance/Peyronies-Disease.pdf>.
- Xiaflex® (collagenase clostridium histolyticum) [Prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; 8/2022.

(7) Policy Update

Date of last review: 2Q2024

Date of next review: 2Q2025

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*