blue california
Promise Health Plan

collagenase clostridium histolyticum (Xiaflex)

Medical Benefit Drug Policy

Place of Service

Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: MISCELLANEOUS THERAPEUTIC AGENTS
Mechanism of Action: Collagenases are proteinases that hydrolyze collagen in its native triple helical conformation under physiological conditions resulting in lysis of collagen deposits.
HCPCS:
J0775:Injection, collagenase, clostridium histolyticum, 0.01 mg
How Supplied:
0.9 mg (Single-use glass vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Dupuytren's Contracture
- Peyronie's Disease

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Dupuytren's Contracture

Meets medical necessity if all the following are met:

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:

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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
Meets medical necessity if all the following are met:
1. Prescribed by or in consultation with a urologist
2. Meets both of the following:
   a. Palpable plaque
   b. Curvature deformity of ≧ 30 degrees at the start of therapy

Covered Doses:
Treatment cycle: Up to 2 injections of 0.58 mg Xiaflex injected into the target plaque, administered 1 to 3 days apart.

Coverage Period:
Initial:
One treatment cycle (consists of two injections per plaque)

Reauthorization for another treatment cycle (consists of two injections) if the following below are met:
1. Prescribed by or in consultation with a urologist
2. Patient is responding to therapy (e.g. stabilization of disease defined by relief from pain, improvement in curvature deformity, etc.)
3. Curvature deformity of > 15 degrees remaining since last treatment cycle

Reauthorization can be requested for additional treatment cycles to treat the same plaque if the patient has received less than eight injections. One plaque can be treated with up to four treatment cycles (8 injections) when criteria is met. Additional treatment cycles must be given at least 6-weeks from the previous treatment cycle.

ICD-10:
N48.6

Additional Information

- Xiaflex is available for the treatment of Peyronie's disease only through a restricted program called the XIAFLEX REMS Program.

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. 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.
4. Xiaflex (collagenase clostridium histolyticum) [prescribing information]. Rochester, MI: Endo USA; April 2024.

Review History

Date of Last Annual Review: 2Q2026

Changes from previous policy version:

- no clinical changes following annual review

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee