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Coverage Policy Number IP0143

Collagenase Clostridium Histolyticum

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for collagenase clostridium histolyticum intralesional injection (**Xiaflex®**).

Medical Necessity Criteria

Collagenase clostridium histolyticum (Xiaflex) is considered medically necessary when **ONE** of the following is met (**1 or 2**):

1. **Dupuytren's Contracture.** Individual meets **ALL** of the following criteria:
 - A. Age 18 years or older
 - B. Treatment of symptomatic Dupuytren's contracture with **BOTH** of the following:
 - i. Presence of a palpable cord

- ii. Functional impairment as manifested by a metacarpophalangeal (MCP) joint or proximal interphalangeal (PIP) joint contracture of 20 degrees or greater at baseline (prior to initial injection of Xiaflex)
- C. As part of the current treatment course, the individual will NOT be treated with more than a total of three injections (maximum) per affected cord
- D. Medication is administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture

Dosing. Dose meets **ALL** of the following:

- 1. The dose is 0.58 mg per injection into an affected cord
- 2. A maximum of two cords (up to 1.16 mg) are injected per treatment visit. If there are other affected cords in the same hand, treatment may be administered to those on a different day.
- 3. For each affected cord, subsequent doses are administered no sooner than 4 weeks following the previous Xiaflex injection

2. **Peyronie's Disease.** Individual meets **ALL** of the following criteria:

- A. Age 18 years or older
- B. Presence of a palpable plaque
- C. Meets **ONE** of the following:
 - i. At baseline (prior to initial injection of Xiaflex), the individual has a penile curvature deformity of at least 30 degrees
 - ii. Individual who has received prior treatment with Xiaflex and has a penile curvature deformity of at least 15 degrees
- D. Will NOT be treated with more than a total of 8 injections (maximum) per Peyronie's plaque
- E. Medication is administered by a healthcare provider experienced in the treatment of male urological diseases

Dosing. Dose meets **BOTH** of the following:

- 1. Up to a total of eight 0.58 mg injections per Peyronie's plaque (four dosing cycles, each consisting of two 0.58 mg injections given 1 to 3 days apart)
- 2. Cycles are separated by at least 6 weeks from the previous Xiaflex cycle

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration:

- **Dupuytren's Contracture:** up to a maximum of three injections per cord
- **Peyronie's Disease:** up to a maximum of 4 treatment cycles (or 8 injections) per Peyronie's plaque

Reauthorization approval duration:

- **Dupuytren's Contracture:** not applicable
- **Peyronie's Disease:** not applicable

Conditions Not Covered

Collagenase clostridium histolyticum (Xiaflex) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

1. **Cosmetic Uses** (e.g., cellulite of buttocks).
2. **Retreatment for Peyronie's Disease.** For Peyronie's disease, the safety of more than one treatment course (8 injections) per plaque is unknown.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|----------------|--|
| 20527 | Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture) |

| HCPCS Codes | Description |
|----------------|--|
| J0775 | Injection, collagenase clostridium histolyticum, 0.01 mg |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

Background

OVERVIEW

Xiaflex, a combination of bacterial collagenases, is indicated for the following uses:¹

- **Dupuytren's contracture** with a palpable cord in adults.
- **Peyronie's disease** with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy in adult men.

Disease Overview

Dupuytren's contracture is a disorder of the palmar and digital fascia of the hand.² Abnormal deposition of collagen initially causes nodules in the palm of the hand, which may thicken and lead to formation of cords. As the disease progresses, the cords gradually contract, leading to flexion deformities of the fingers. Joint contractures are typically painless but are associated with significant functional impairment. In clinical studies of Dupuytren's contracture, patients were eligible to participate if they had a finger contraction of 20 degrees to 100 degrees in a metacarpophalangeal joint or 20 degrees to 80 degrees in a proximal interphalangeal joint.¹

Peyronie's disease is an acquired penile abnormality caused by fibrosis of the tunica albuginea, which may lead to pain, deformity, erectile dysfunction, and/or distress.³ Peyronie's disease has a variable course; for most patients, pain will resolve over time without intervention but curvature deformities are less likely to resolve without treatment. Intralesional therapy with Xiaflex may be used to treat curvature associated with Peyronie's disease and is supported by American Urological Association guidelines (2015).

Dosing Considerations

For treatment of Dupuytren's contracture, the dose of Xiaflex is 0.58 mg per injection into a palpable cord with a contracture of a metacarpophalangeal or proximal interphalangeal joint.¹ Two palpable cords affecting two joints

or one palpable cord affecting two joints in the same finger may be injected per treatment visit. Injections may be administered up to three times per cord at approximately 4-week intervals.

For treatment of Peyronie’s disease, one treatment course consists of four cycles.¹ Each cycle consists of two Xiaflex injection procedures (1 to 3 days apart). Up to four cycles of Xiaflex may be administered, given at approximately 6-week intervals. The safety of more than one treatment course (8 total injections) is unknown. If the curvature deformity is less than 15 degrees after the first, second, or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles should not be administered.

References

1. Xiaflex® intralesional injection [prescribing information]. Malvern, PA: Endo Pharmaceuticals; August 2022.

2. Brazzelli M, Cruickshank M, Tassie E, et al. Collagenase clostridium histolyticum for the treatment of Dupuytren’s contracture: systematic review and economic evaluation. Southampton (UK): NIHR Journals Library; 2015 Oct. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK326596/>. Accessed on August 16, 2024.

3. Nehra A, Alterowitz R, Culkin D, et al. Peyronie’s disease: AUA guideline. *J Urol*. 2015;194(3):745-753.

Revision Details

| Type of Revision | Summary of Changes | Date |
|-------------------|--|------------|
| Selected Revision | No criteria changes; minor updates to policy format. | 12/01/2024 |
| Selected Revision | Updated Coding: Added CPT Codes 20527, 26341 | 2/15/2025 |
| Selected Revision | Updated Coding: Removed CPT 26341 | 2/28/2025 |

The policy effective date is in force until updated or retired.

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