Clinical Policy: Collagenase Clostridium Histolyticum (Xiaflex)

Reference Number: PA.CP.PHAR.82
Effective Date: 10/2018
Last Review Date: 07/2024

Description
Collagenase clostridium histolyticum (Xiaflex®) is a combination of bacterial collagenases.

FDA Approved Indication(s)
Xiaflex is indicated for the treatment of:
- Adult patients with Dupuytren's contracture (DC) with a palpable cord
- Adult men with Peyronie's disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

Policy/Criteria
It is the policy of PA Health & Wellness that Xiaflex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dupuytren's Contracture (must meet all):
1. Diagnosis of DC with a palpable cord;
2. Prescribed by or in consultation with a healthcare provider experienced in injection procedures of the hand and in the treatment of DC;
3. Age ≥ 18 years;
4. Member has not received surgical treatment (e.g., fasciectomy, fasciotomy) on the selected primary joint within the last 90 days;
5. If two injections (two vials) are requested, they are for one of the following (a or b):
   a. One cord affecting two joints in the same finger;
   b. Two cords affecting two joints in the same hand;
6. Dose does not exceed 0.58 mg per injection (one vial per injection).

Approval duration: 3 months (up to 2 injections)

B. Peyronie's Disease (must meet all):
1. Diagnosis of PD with both of the following (a and b):
   a. Palpable plaque;
   b. Curvature deformity of ≥ 30 degrees at the start of therapy;
2. Prescribed by or in consultation with a healthcare provider experienced in the treatment of male urological diseases;
3. Age ≥ 18 years;
4. Dose does not exceed 0.58 mg per injection (one vial per injection).

Approval duration: 3 months (up to 2 injections)

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Dupuytren's Contracture (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Last treatment was ≥ 4 weeks ago;
3. Member will not receive more than three total injections per affected cord;
4. Request is for one or both of the following:
   a. Metacarpophalangeal (MP) or proximal interphalangeal (PIP) contracture remains in affected cord since previous injection and the contracture is > 5 degrees;
   b. A different MP or PIP contracture will be injected;
5. If two injections (two vials) are requested, use is for one of the following (a or b):
   a. One cord affecting two joints in the same finger;
   b. Two cords affecting two joints in the same hand;
6. Member has not received surgical treatment (e.g., fasciectomy, fasciotomy) on the selected primary joint within the last 90 days;
7. If request is for a dose increase, new dose does not exceed 0.58 mg per injection (one vial per injection).

Approval duration: 3 months (up to 2 injections, total of 3 injections per affected cord)

B. Peyronie's Disease (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documented curvature deformity of ≥15 degrees remaining since last treatment cycle;
3. Last treatment cycle was ≥ 6 weeks ago;
4. Has received < 4 treatment cycles (< 8 injections [2 injections per cycle]);
5. If request is for a dose increase, new dose does not exceed 0.58 mg per injection (one vial per injection).

Approval duration: 3 months (up to 2 injections)

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DC: Dupuytren's contracture
FDA: Food and Drug Administration
MP: metacarpophalangeal joint
PD: Peyronie's disease
PIP: proximal interphalangeal joint

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Peyronie's plaques that involve the penile urethra; hypersensitivity to Xiaflex or collagenase used in other therapeutic applications.
- Boxed warning(s): corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DC	0.58 mg per injection intralesionally into a palpable cord with a contracture of a MP joint or a PIP joint Injections (0.58 mg) and finger extension procedures (24 to 72 hours after injection) may be administered up to 3 times per cord at approximately 4-week intervals. Up to 2 injections in the same hand may be performed during a treatment visit. Two palpable cords affecting 2 joints may be injected or 1 palpable cord affecting 2 joints in the same finger may be injected at 2 locations during a treatment visit. If a patient has other palpable cords with contractures of the MP or PIP joints, these cords may be injected at other treatment visits approximately 4 weeks apart.	0.58 mg/dose
PD	0.58 mg per injection intralesionally administered into a Peyronie's plaque; if more than one plaque is present, inject into the plaque causing the curvature deformity. A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of two Xiaflex injection procedures and one penile modeling procedure. The second Xiaflex injection procedure is performed 1 to 3 days after the first. The penile modeling procedure is performed 1 to 3 days after the second injection of the treatment cycle. The interval between treatment cycles is approximately six weeks. The treatment course therefore, consists of a maximum of 8 injection procedures and 4 modeling procedures. If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if the healthcare provider determines that further treatment is not clinically indicated, then the subsequent treatment cycles should not be administered. The safety of more than one treatment course of Xiaflex is not known.	0.58 mg/dose

V. Product Availability

Lyophilized powder for reconstitution (single-use glass vials): 0.9 mg of collagenase clostridium histolyticum

VI. References

1. Xiaflex Prescribing Information. Malvern, PA: Endo Pharmaceuticals, Inc.; July 2023. Available athttps://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125338s111lbl.pdf. Accessed May 13, 2024.
2. Schulze SM and Tursi JP. Postapproval clinical experience in the treatment of Dupuytren's contracture with collagenase clostridium histolyticum (CCH): the first 1,000 days. Hand. 2014; 9: 447-458.
3. Collagenase Drug Monograph. Clinical Pharmacology. Available at: https://www.clinicalkey.com/pharmacology/. Accessed April 26, 2023.
4. Nehra A, Alterowitz R, Culkin DJ, et al. American Urological Association Education and Research, Inc. Peyronie's Disease: AUA Guideline. J Urol. 2015 Sep;194(3):745-53. doi: 10.1016/j.juro.2015.05.098.
5. Manka MG, White LA, Yafi FA, et al. Comparing and Contrasting Peyronie's Disease Guidelines: Points of Consensus and Deviation. J Sex Med 2021; 18: 363-375.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date
3Q 2018 annual review: Dupuytren's contracture – removed "table top test" and flexion contracture degree requirements (clinical trial inclusion criteria) as specialist involvement is required; references reviewed and updated.	04/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
3Q 2020 annual review: added age limit ≥18 years of age; references reviewed and updated.	07/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
3Q 2022 annual review: no significant changes; references reviewed and updated.	07/2022
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
3Q 2024 annual review: no significant changes; references reviewed and updated.	07/2024