Clinical Policy: Collagenase Clostridium Histolyticum (Xiaflex)
Reference Number: LA.PHAR.82
Effective Date: 10.30.22
Last Review Date: 04.17.24 ~~06.28.23~~ Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections 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~~.~~:

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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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., ~~new~~newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria.
2. Last treatment was ≥ 4 weeks ago.
3. Member has not received more than two 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 Louisiana Healthcare Connections benefit or member has previously met initial approval criteria.
2. Documented curvature deformity of ≥ 15 degrees remaining since last treatment cycle~~.~~;
3. Last treatment cycle was ≥ 6 weeks ago~~.~~;
4. Member has received < 4 treatment cycles (i.e~~.~~, < 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).

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Approval duration: 3 months (up to 2 injections)

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., ~~new~~newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy LA.PMN.53

IV. 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.

V. 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 ~~later~~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	0.58 mg/dose

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Indication	Dosing Regimen	Maximum Dose
	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.	
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

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VI. Product Availability

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

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VII. References

1. Xiaflex Prescribing Information. Malvern, PA: Endo Pharmaceuticals, Inc.; ~~November 2019.~~August 2022. Available at ~~https://www.xiaflex.com/.~~https://www.xiaflex.com/. Accessed ~~May 3, 2022.~~April 24, 2023.
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: ~~http://www.clinicalpharmacology-ip.com.~~https://www.clinicalkey.com/pharmacology/. Accessed ~~May 3, 2022~~April 26, 2023.
4. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's ~~Disase~~Disease: American Urological Association (AUA) Guideline, 2015. Available at: ~~https://www.auanet.org/guidelines/guidelines/peyronies-disease-~~

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~~guideline.~~https://www.auanet.org/guidelines/guidelines/peyronies-disease-guideline. Accessed ~~May 3, 2022.~~April 26, 2023.

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	LDH Approval Date
Converted corporate to local policy.	09.22	10.30.22
Template changes applied to other diagnoses/indications and continued therapy section. Added blurb that this policy for medical benefit only.	06.27.23	10.05.23
Annual review: no significant changes; references reviewed and updated.	04.17.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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