Pharmacy Management Drug Policy

SUBJECT: Xiaflex (collagenase clostridium histolyticum)
POLICY NUMBER: PHARMACY-106
EFFECTIVE DATE: 08/01/2023
LAST REVIEW DATE: 08/13/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Fibroproliferative disorders, characterized by excessive collagen deposits, can affect the musculoskeletal system, causing pain, limiting joint range of motion, and negatively impacting quality of life. Examples of these fibrotic tissue disorders include Dupuytren's contracture, adhesive capsulitis, and Peyronie's disease.

Collagenases, enzymes that digest native collagen and lead to the disruption of contracted cords, are being investigated as a non-surgical treatment for fibroproliferative disorders. Injection of collagenase clostridium histolyticum, a bacterial collagenase, is intended to provide a non-operative treatment option and is usually an office-based procedure.

Xiaflex (collagenase clostridium histolyticum, CCH) is FDA-approved for the treatment of Dupuytren's contracture with a palpable cord. The FDA labeling for Xiaflex states that up to three injections at four-week intervals may be given into a palpable Dupuytren's cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint. This should be followed by manual manipulation of the affected joint to attempt rupture of the cord.

Additionally, Xiaflex has been FDA-approved for treatment of men with Peyronie's disease who have a penile curvature of at least 30 degrees. The dose of Xiaflex is 0.58 mg per injection, administered into a Peyronie's plaque. Up to eight injections (four treatment cycles) may be administered in the course of treatment. Also, a penile modeling procedure is recommended after every treatment cycle of two injections, in an effort to further disrupt the plaque. Expert opinion defines "functionally straight" as penile curvature less than or equal to 20 degrees (Krishnappa et al., 2019).

In a prospective cohort study by Wymer and colleagues (2018), 115 patients with Peyronie's disease who completed at least two CCH cycles were analyzed for improvement in penile curvature, to assess for characteristics predictive of treatment success. Thirty-four of the 115 men included were found to have calcification. Patients with calcified plaque were more likely to have dorsal curvature and severe erectile dysfunction. Patients with noncalcified plaque and curvature of at least 60 degrees had the greatest improvement in curvature (defined as improvement in curvature greater than 20%). The authors concluded that calcification is one of the strongest predictors for CCH failure and that men with baseline curvature greater than 60 degrees are approximately 2.5 times more likely to experience a 20% or more improvement, compared to lesser curvatures.

Dupuytren's Contracture

1. Must be 18 years of age or older
2. Must be used for the treatment of Dupuytren's contracture in either the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joint when there is a palpable palmar cord.
3. Must have documentation that the contracture is at least 20 degrees prior to initiating Xiaflex therapy
4. Provider must attest that **all the following (a, b and c) are met:**
    a. The provider is experienced in
        i. Injection procedures of the hand
        ii. Treatment of patients with Dupuytren's contracture
    b. The provider has completed the necessary training to administer Xiaflex
    c. The **provider** and **healthcare site** are enrolled in the **Xiaflex Managed Distribution Program for Dupuytren's contracture**
5. The provider must specify the location of the cord being treated on the hand; indicating the hand, finger(s) and joint(s) affected
6. The dose of Xiaflex is 0.58 mg per injection into a palpable cord with a contracture of a MP joint or a PIP joint. (See prescribing information for complete details)
    a. Each vial of Xiaflex (supplied as 0.9 mg) and sterile diluent should only be used for a single injection.
    b. Approximately 24 to 72 hours after injection, a finger extension procedure should be performed if a contracture persists to facilitate cord disruption.
    c. If two joints on the same hand are to be treated during a treatment visit, separate vials and syringes should be used for each reconstitution and injection.
7. Xiaflex injection is administered at four-week intervals for a total of 3 injections per cord/joint.
    a. **Xiaflex will not be authorized for retreatment beyond a total of 3 injections per cord/joint.**
8. If requesting two injections (two vials) in the same hand for a single treatment visit, one of the following must be met:
        i. The patient has two palpable cords affecting two joints on the same hand **OR**
        ii. The patient has one palpable cord affecting two joints in the same finger
9. Approval duration as follows:
    a. For all **non-Managed Medicaid/HARP** lines of business: 6 months (**for a total of 3 injections per cord/joint)**, to allow adequate time to complete treatment.
    b. For **Managed Medicaid/HARP:** 4 weeks (**limited to a maximum of 2 injections in the same hand for a single treatment visit as outlined in criterion #8**)
10. **Managed Medicaid/HARP ONLY:** Per New York State Department of Health requirements, requests for Xiaflex require eligibility verification via EDVS system (13 years of age and older).

Peyronie's Disease

1. Must be 18 years of age or older
2. Must have a diagnosis of Peyronie's disease
3. Must have stable disease, defined by no change in symptoms (e.g., penile curvature and pain) for at least three months
4. Must have the presence of a palpable plaque at the site of maximum curvature
5. Must have documentation at the start of therapy of a curvature deformity between 30 and 90 degrees that causes a functional deficit (e.g., an inability to engage in sexual intercourse, sexual intercourse is painful for either partner, or penile pain) not attributable to other causes
6. Provider must attest that Xiaflex will be used in combination with a penile modeling procedure
7. Provider must attest both (a and b) are met:
    a. The provider has experience in the treatment of male urological diseases

   b. The **provider** and **healthcare site** are certified through the **Xiaflex REMS Program**.
8. The dose of Xiaflex is 0.58 mg (supplied as a 0.9 mg vial) per injection 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 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 6 weeks. The treatment course, therefore, consists of a maximum of 8 injection procedures and 4 modeling procedures (four treatment cycles). (See prescribing information for complete details)
9. Xiaflex will be authorized for a maximum of four treatment cycles (two Xiaflex injection procedures and one penile modeling procedure per cycle), each separated by six weeks. **Xiaflex will not be authorized beyond four treatment cycles (8 injections) per plaque.**
10. Approval duration will be for 12 months (for a total of 8 injections) to allow adequate time to complete treatment.
11. Retreatment with Xiaflex will not be authorized when the penis is functionally straight (i.e., the curvature deformity is less than or equal to 20 degrees) after the first, second or third treatment cycle, or if further treatment is not clinically indicated.
12. **Managed Medicaid/HARP ONLY: The use of Xiaflex for the treatment of Peyronie's disease is not a covered benefit.**

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

HCPCS Codes:

J0775 - Injection, collagenase, clostridium histolyticum, 0.01 mg

Approval Time Periods:

Line of Business	Medical approval time-period
Medicaid/HARP	**Dupuytren's Contracture**: Approval duration of 4 weeks (limited to a maximum of 2 injections in the same hand for a single treatment visit as outlined in criterion #8 of the Dupuytren's section) **Peyronie's Disease: For Managed Medicaid/HARP ONLY**: The use of Xiaflex for the treatment of Peyronie's disease is not a covered benefit.
Commercial/Exchange/Essential/CHP	**Dupuytren's Contracture**: up to a maximum of three injections per cord/joint for an approval duration of 6 months to allow adequate time to complete treatment. **Peyronie's Disease:** up to a maximum of 4 treatment cycles (8 injections) per Peyronie's plaque for an approval duration of 12 months to allow adequate time to complete treatment
Medicare	

POLICY GUIDELINES:

1. Xiaflex is administered by a health care professional and will be reviewed under the **medical benefit.**
2. Xiaflex will not be covered for any other indication other than those listed in the policy section.

3. Xiaflex will not be covered for cosmetic use. Cosmetic drugs are drugs that are used to improve a patient's appearance and/or self-esteem. Cosmetic drugs are considered not medically necessary. A drug can be considered cosmetic either based on its FDA approved indication, compendia reference or off-label support.
4. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
5. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
6. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
7. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
8. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, and imaging.
    - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
9. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
10. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
11. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
12. The requested site of care may impact approval timeframe and subject to review.

UPDATES:

Date:	Revision:
08/13/2026	Reviewed / P&T Committee Review & Approval
06/01/2026	Revised
01/15/2026	Revised
11/19/2025	Revised
08/14/2025	Reviewed / P&T Committee Review & Approval
03/06/2025	Revised

12/19/2024	Revised
09/13/2024	Revised
08/27/2024	Revised
08/15/2024	Reviewed / P&T Committee Review & Approval
06/20/2024	Revised
08/24/2023	P&T Committee Review & Approval
08/09/2023	Revised
08/01/2023	Revised / Implemented
11/17/2022	P&T Committee Review & Approval
11/2022	Created

REFERENCES:

In addition to the full FDA approved prescribing information for each individual drug, the following references have been utilized in creating this policy and specific drug criteria:

1. Krishnappa P, et al. Surgical management of Peyronie's disease with co-existent erectile dysfunction. Sex Med 2019 Sep 17. pii: S2050-1161(19)30178-3.
2. Wymer K, et al. Plaque calcification: an important predictor of collagenase clostridium histolyticum treatment outcomes for men with Peyronie's disease. Urology 2018 Sep;119:109-114.W