

# Clinical Policy: Collagenase Clostridium Histolyticum (Xiaflex)

Reference Number: CP.PHAR.82

Effective Date: 10/11

Last Review Date: 12/16

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

## Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for collagenase clostridium histolyticum (Xiaflex®).

## Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Xiaflex is **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

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

1. Prescribed by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture (DC);
2. Documented diagnosis of DC with a palpable cord and all of the following:
  - a. Positive "table top test" (inability to simultaneously place affected finger and palm flat against a table top);
  - b. Flexion contracture  $\geq 20$  degrees in metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of affected finger;
  - c. If two injections (two vials) are requested, they are for one of the following:
    - i. One cord affecting two joints in the same finger;
    - ii. Two cords affecting two joints in the same hand;
3. Prescribed dose of Xiaflex does not exceed 0.58 mg per joint;
4. Has not had surgical treatment on the selected primary joint within the last 90 days;
5. No history of hypersensitivity to Xiaflex or to collagenase used in any other therapeutic applications.

**Approval duration: up to 2 injections (one vial per injection)**

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

1. Prescribed by a healthcare provider experienced in the treatment of male urological diseases and who has completed required training for use of Xiaflex in the treatment of Peyronie's disease (PD) through the Xiaflex risk evaluation and mitigation strategy (REMS) program;
2. Documented diagnosis of PD with both of the following:
  - a. Palpable plaque;
  - b. Curvature deformity of  $\geq 30$  degrees at start of therapy;
3. Prescribed dose of Xiaflex does not exceed 0.58 mg per injection;
4. Treatment is not intended for plaques that involve the penile urethra;
5. No history of hypersensitivity to Xiaflex or to collagenase used in any other therapeutic applications.

**Approval duration: up to 2 injections (one vial per injection)**

**C. Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.

## **II. Continued Approval**

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Last treatment was  $\geq 4$  weeks ago;
3. Request is for one or both of the following:
  - a. MP or 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 that has a positive table top test and a flexion contracture of  $\geq 20$  degrees;
4. If 2 injections are requested, the injections are for one cord affecting two joints in the same finger or two cords affecting two joints in the same hand;
5. After requested injection, affected cord will have received no more than 3 total injections;
6. Prescribed dose of Xiaflex does not exceed 0.58 mg per joint;
7. Has not had surgery on the selected primary joint in the last 90 days;
8. No history of hypersensitivity to Xiaflex or to collagenase used in any other therapeutic applications.

**Approval duration: up to 2 injections (one vial per injection)**

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documented curvature deformity of  $\geq 15$  degrees remaining since last treatment cycle;
3. Last treatment cycle was  $\geq 6$  weeks ago;
4. Has received  $< 4$  treatment cycles ( $< 8$  injections [2 injections per cycle]);
5. Prescribed dose of Xiaflex does not exceed 0.58 mg per injection per plaque;
6. No history of hypersensitivity to Xiaflex or to collagenase used in any other therapeutic applications.

**Approval duration: up to 2 injections (one vial per injection)**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

## **Background**

*Description/Mechanism of Action:*

**CLINICAL POLICY**  
**Collagenase Clostridium Histolyticum**

Xiaflex contains purified collagenase clostridium histolyticum, consisting of two microbial collagenases in a defined mass ratio, Collagenase AUX-I and Collagenase AUX-II, which are isolated and purified from the fermentation of Clostridium histolyticum bacteria. Collagenases are proteinases that hydrolyze collagen in its native triple helical conformation under physiological conditions, resulting in lysis of collagen deposits. Injection of Xiaflex into a Dupuytren’s cord, which is comprised mostly of collagen, may result in enzymatic disruption of the cord. The signs and symptoms of Peyronie’s disease are caused by a collagen plaque. Injection of Xiaflex into a Peyronie’s plaque, which is comprised mostly of collagen, may result in enzymatic disruption of the plaque. Following this disruption of the plaque, penile curvature deformity and patient bother caused by Peyronie’s disease are reduced.

*Formulations:*

Xiaflex is available in single-use, glass vials containing 0.9 mg of collagenase clostridium histolyticum. Each vial also contains 0.5 mg of hydrochloric acid, 18.5 mg of sucrose, and 1.1 mg of tromethamine.

- Xiaflex is supplied as a sterile lyophilized powder (white cake) intended for reconstitution with the supplied sterile diluent (0.3 mg/mL calcium chloride dihydrate in 0.9% sodium chloride) prior to intralesional injection into a Dupuytren’s cord or a Peyronie’s plaque.

*FDA Approved Indications:*

Xiaflex is a combination of bacterial collagenases/intralesional injectable formulation indicated for:

- Treatment of adult patients with Dupuytren’s contracture with a palpable cord;
- Treatment of adult men with Peyronie’s disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

**Appendices**

**Appendix A: Abbreviation Key**

- DC: Dupuytren’s contracture
- MP: metacarpophalangeal joint
- PD: Peyronie’s disease
- PIP: proximal interphalangeal joint
- REMS: risk evaluation and mitigation strategy

**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

**CLINICAL POLICY**  
**Collagenase Clostridium Histolyticum**

Reviews, Revisions, and Approvals	Date	Approval Date
No clinical changes	11/12	12/12
Converted embedded SGM document into Centene clinical policy template	08/13	
Added treatment of Peyronie’s disease	12/13	01/14
Figure 1 :Removed the requirement that Xiaflex must be ordered through the REMS program Added the requirement for positive table top test Removed requirement that patient must not be a surgical candidate Figure 3: Removed the requirement that Xiaflex must be ordered through the REMS program; Added Appendix with definition of table top test Clinical Information: Added information about Xiaflex managed distribution program and REMS program for both FDA approved indication Figure 2: rephrased question on how many injections received and clarified if contracture still remains rather than a reduction in contracture	12/14	01/15
Converted policy to new template. DC initial auth criteria: added question about provider specialty per PI; removed question about underlying neuromuscular disorder affecting the hands - not in PI; removed thumb exclusion; added contraindications; changed approval from one injection to up to two total injections (same hand) visit. DC re-auth criteria: changed re-authorization approval of one injection to up to two injections but limited to not more than 3 injections in any one cord per PI; added criteria for a different contracture to be treated. PD criteria: added question about provider specialty and training per PI; added contraindications.	12/15	01/16
Converted policy to new template. Removed age limitation and added max dose for both indications.	12/16	01/17

**References**

1. Xiaflex Prescribing Information. Malvern, PA: Auxilium Pharmaceuticals, Inc.; August 2016. Available at [http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex\\_prescribing\\_information.pdf](http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex_prescribing_information.pdf). Accessed November 22, 2016.
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.

**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

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policy; and other available clinical information. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

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**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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