

Clinical Policy: Collagenase Clostridium Histolyticum (Xiaflex)

Reference Number: PA.CP.PHAR.82

Effective Date: 01/18

Last Review Date: 12/16

[Coding Implications](#)

[Revision Log](#)

Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for collagenase clostridium histolyticum (Xiaflex[®]).

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness 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 ≥ 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 ≥ 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 PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and 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. 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 ≥ 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 Pennsylvania Health and 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. 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 Pennsylvania Health and 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.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

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. 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.