

# Clinical Criteria

<b>Subject:</b>	Xiaflex (collagenase clostridium histolyticum) injection		
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## Overview

This document addresses the use of Xiaflex (collagenase clostridium histolyticum) which is a biologic that hydrolyzes native collagen. When injected into fibrous cords, Xiaflex can lead to a reduction in contracture and improvement in range of motion of the affected joints. Xiaflex is approved for the treatment of Dupuytren's contracture and Peyronie's disease.

Dupuytren's disease is a progressive fibroproliferative disorder of an unknown origin affecting the hands causing permanent flexion contracture of the fingers. Surgery (fasciectomy) has been the mainstay treatment for Dupuytren's. An alternative to invasive surgery is injection of collagenase to break up the fibrous cord responsible for the contracture.

Peyronie's disease is a connective tissue disorder which involves the growth of fibrous plaque in the soft tissue of the penis which can lead to symptoms such as penile curvature and pain. The 2015 American Urological Association (AUA) Peyronie's Disease guidelines recommend intralesional Xiaflex in combination with modeling by the clinician and patient for the reduction of penile curvature in patients with stable Peyronie's disease, penile curvature  $>30^{\circ}$  and  $<90^{\circ}$ , and intact erectile function (with or without the use of medications).

Xiaflex has a black box warning for corporal rupture (penile fracture) or other serious penile injury when administered for the treatment of Peyronie's disease. Due to the risks of corporal rupture and other serious penile injury, Xiaflex is only available for the treatment of Peyronie's disease through a restricted REMS program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the Xiaflex REMS website: <http://www.xiaflexrems.com>.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Xiaflex (collagenase clostridium histolyticum)

Requests for injection of Xiaflex (collagenase clostridium histolyticum) may be approved for the following:

- I. Individual has a diagnosis of Dupuytren's contracture; **AND**
  - II. Product will be injected into a palpable palmar cord which has been documented to impair the individual's functional activities and measures either:
    - A. 20 degrees or more at the metacarpophalangeal joint; **OR**
    - B. 20 degrees or more at the proximal interphalangeal joint;
- AND**
- III. The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals;
- OR**
- IV. Individual has a diagnosis of Peyronie's disease; **AND**
  - V. Disease is stable as defined by symptoms (such as, but not limited to penile curvature and pain) for at least 6 months (AUA); **AND**
  - VI. Penile curvature is greater than or equal to 30 degrees and less than or equal to 90 degrees (AUA); **AND**

- VII. Individual has intact erectile function with or without the use of medications (AUA); **AND**  
VIII. Individual has palpable penile plaque(s).

Requests for Xiaflex (collagenase clostridium histolyticum) may not be approved ~~when the above criteria are not met and for all other indications for the following:~~

- I. ~~Individual is using for cosmetic indications, including, but not limited to, the treatment of cellulite;~~ **OR**  
II. ~~When the above criteria are not met and for all other indications.~~

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### CPT

<b>20527</b>	Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture)
<b>26341</b>	Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord

### HCPCS

<b>J0775</b>	Injection, collagenase, clostridium histolyticum, 0.01 mg [Xiaflex]
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### ICD-10 Diagnosis

<b>M72.0</b>	Palmar fascial fibromatosis (Dupuytren)
<b>N48.6</b>	Induration penis plastica (Peyronie's disease)

## Document History

Revised: 09/14/2020

Document History:

- 09/14/2020 – Annual Review: Update non-approvable criteria to restrict the use of Xiaflex for cosmetic indications. Coding Review: No changes.
- 09/09/2019 – Annual Review: Minor wording and formatting changes. Coding Reviewed: No changes.
- 08/17/2018 – Annual Review: Minor wording and formatting changes.

## References

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
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- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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- Nehra A, Alterowitz R, Culkun DJ, et al: American Urological Association Education and Research, Inc., Peyronie's Disease: AUA Guideline. J Urol. 2015; 194(3):745-753. Accessed: August 7, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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