

Medical Drug Clinical Criteria

Subject:	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° and <90°, 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. Documentation is provided that product will be injected into a palpable palmar cord that impairs the individual's functional activities; **AND**
- III. Documentation is provided that the palpable cord measures either:
 - A. 20 degrees or more at the metacarpophalangeal joint; **OR**
 - B. 20 degrees or more at the proximal interphalangeal joint;

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. Documentation is provided that 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. Documentation is provided that individual has palpable penile plaque(s).

Xiaflex (collagenase clostridium histolyticum) may not be approved for the following:

- I. Individual is using for cosmetic indications, including, but not limited to, the treatment of cellulite; **OR**
- II. Individual is using for Peyronie's plaques that involve the penile urethra; **OR**
- III. When the above criteria are not met and for all other indications.

Quantity Limits

Xiaflex Quantity Limits

Drug	Limit per Indication
Xiaflex (collagenase clostridium histolyticum) 0.9mg vial	Dupuytren's Contracture: up to 2.32 mg per 28 days Lifetime Maximum: 3 injections per affected cord
	Peyronie's Curvature: 1.16 mg per 7 days Lifetime Maximum: 8 injections per Peyronie's plaque

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

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

HCPCS

- J0775 Injection, collagenase, clostridium histolyticum, 0.01 mg [Xiaflex]

ICD-10 Diagnosis

- M72.0 Palmar fascial fibromatosis (Dupuytren)
- N48.6 Induration penis plastica (Peyronie's disease)

Document History

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Document History:

- 09/08/2025 – Annual Review: No changes. Coding Reviewed: No changes. 09/09/2024 – Annual Review: No Changes. Coding Reviewed: No changes.
- 09/11/2023 – Annual Review: No Changes. Coding Reviewed: No changes.
- 09/15/2022 – Annual Review: Add quantity limit. Coding Reviewed: No changes.
- 09/13/2021 – Annual Review: Update criteria to include labeled contraindication restricting use involving the penile urethra. Coding review: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 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

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.

2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. American Urological Association. *J Urol* 2015; 194(3):745-753. Available at: <https://www.auanet.org/guidelines/peyronies-disease-guideline> Accessed August 28, 2025.
5. Peimer CA, Blazar P, et al. Dupuytren contracture recurrence following treatment with collagenase clostridium histolyticum (CORDLESS study): 3-year data. *J Hand Surg Am.* 2013; 38:12-22.
6. Räsänen MP, Leppänen OV, Soikkeli J, et al. Surgery, Needle Fasciotomy, or Collagenase Injection for Dupuytren Contracture: A Randomized Controlled Trial. *Ann Intern Med* 2024; 177:280.

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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