Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
collagenase clostridium histolyticum (Xiaflex®) injection	**MP-RX-FP-104-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	**11/30/2023** **Last Review Date:** **10/21/2026**	**10/21/2026** **Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of collagenase clostridium histolyticum (Xiaflex®) injection, a bacterial collagenase approved by the Food and Drug Administration (FDA) for the treatment of Dupuytren's contracture and Peyronie's disease.

Background Information:

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 warming 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 rupptureand other serious penile injury. Xiaflex is only available for the treatment of Peyronie's disease thought restricted REMS program. Additional information and forms for individuals, prescribers and pharmacists may be found on the Xiaflex REMS website: http://www.Xiaflexrems.com.

Approved Indications

A. Dupuytren's contracture with a palpable cord
B. Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

Other Uses

A. None.

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Medical Necessity Guidelines:

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.

Collagenase clostridium histolyticum (Xiaflex®) injection

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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).

B. Criteria For Continuation of Therapy

Continuation requests for Xiaflex may be approved if the following criteria are met:

i. Progress notes or clinical documentation of patient's safety and clinical response to therapy.

C. Authorization Duration

i. Dupuytren's contracture
   A. Initial Approval Duration: 6 months
   B. Reauthorization Approval Duration: 6 months to complete a treatment course
ii. Peyronie's disease
   A. Initial Approval Duration: 12 months
   B. Reauthorization Approval Duration: 12 months to complete a treatment course

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1. If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles should not be administered.

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Xiaflex (collagenase clostridium histolyticum) 0.9mg vial	Dupuytren's Contracture: 1 injection (0.58 mg) per cord per treatment session. Up to two joints in the same hand may be treated during a treatment visit. Maximum: 3 injections per affected cord at approximately 4-week intervals. Peyronie's Disease: 2 injections (0.58 mg each), into the target plaque once on each of 2 days, administered 1 to 3 days apart. Maximum: 8 injections per treatment course (4 cycles), with cycles spaced at least 6 weeks apart.

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

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

HCPCS Codes:

Codes	Description
J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg [Xiaflex]

CPT Codes:

Codes	Description
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

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Reference Information:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 16, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Endo Pharmaceuticals Inc. Xiaflex® (collagenase clostridium histolyticum) for injection, for intralesional use: Prescribing Information. Revised March 2026. Accessed July 16, 2026. https://d1skd172ik98el.cloudfront.net/48a33315-f594-4269-8043-8853d10fb7bf/cb7ae8ba-876c-49e7-8df3-a53219a6597c/cb7ae8ba-876c-49e7-8df3-a53219a6597c_source__v.pdf
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Nehra A, Alterowitz R, Culkin DJ, et al: American Urological Association Education and Research, Inc., Peyronie's Disease: AUA Guideline. J Urol. 2015; 194(3):745-753. Accessed August 28, 2025.
7. 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.
8. Räisänen 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 polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated the Xiaflex medical policy to align with the current Prescribing Information, including revised Peyronie's disease indication language to specify adult men with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. Updated authorization duration for Peyronie's disease to allow completion of the treatment course. Updated the quantity limits table to clarify dosing for Dupuytren's contracture, including treatment of up to two joints in the same hand during a treatment visit, and dosing for Peyronie's disease, including two 0.58 mg injections into the target plaque per treatment cycle, administered 1 to 3 days apart. Coding reviewed: added CPT codes 20527 and 26341. Updated reference information and incorporated the new policy template.	10/15/2026	10/21/2026
Annual Review	Minimal changes; word formatting. Coding reviewed: No changes.	9/5/2025	9/16/2025
Annual Review	Added sections: Other Uses, Criteria for Continuation of Therapy, Conditions not Covered, Therapeutic Alternatives. Update dosage table and references. Wording and formatting changes. Coding Reviewed: no changes.	3/14/2025	4/2/2025
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023