Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
collagenase clostridium histolyticum (Xiaflex®) injection	MP-RX-FP-104-23	☒ MMM MA ☒ MMM Multihealth

Service Category

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

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.

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Approved Indications

A. Dupuytren's contracture with a palpable cord
B. Peyronie's disease

Other Uses

i. N/A

Applicable Codes

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.

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

ICD-10	Description
M72.0	Palmar fascial fibromatosis (Dupuytren)
N48.6	Induration penis plastica (Peyronie's disease)

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

Collagenase clostridium histolyticum (Xiaflex®) injection

A. Criteria for Initial Approval

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).

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. Conditions not Covered

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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D. 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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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 (0.58mg) per cord per treatment session. Maximum: 3 injections per affected cord at approximately 4-week intervals. Peyronie's Curvature: 2 injections (0.58 mg each), 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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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. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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 16, 2022.
6. 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.
7. 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

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Choose an item.		Click or tap to enter a date.	Click or tap to enter a date.
Annual Review 9/27/2024	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 9/27/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023