Original Effective Date: 07/27/2016
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Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C24319-A

Xiaflex (collagenase clostridium histolyticum)

PRODUCTS AFFECTED

Xiaflex (collagenase clostridium histolyticum)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Peyronie's Disease, Dupuytren's Contracture

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PEYRONIE'S DISEASE:
   1. Documented diagnosis of Peyronie's disease with a palpable plaque
      AND

2. Documented penile curvature deformity of at least 30 degrees at baseline (prior to use of Xiaflex)
   AND
3. Documentation member has stable disease (resolution of penile pain and no worsening curvature) for at least 12 months
   AND
4. Documentation member has intact erectile function (with or without use of medications)
   Molina Reviewer Note: Intralesional collagenase with clinician/patient modeling is recommended when the patient has stable PD, a curvature >30 and <90 degrees, and when the patient has intact erectile function (regardless of whether medications are needed to obtain erection or not)
   AND
5. Documentation of treatment failure, serious side effects, or clinical contraindication to a trial of Verapamil intralesional injection
   AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Xiaflex (collagenase clostridium histolyticum) include: Peyronie's plaques that involve the penile urethra, History of hypersensitivity to Xiaflex or to collagenase used in other therapeutic applications]

B. DUPUYTREN'S CONTRACTURE:
1. Documented diagnosis of Dupuytren's contracture with a palpable cord
   AND
2. Documentation of hand and digit(s) being treated
   AND
3. Documentation of a positive "tabletop test" (defined as the inability to simultaneously place the affected finger and palm flat against a tabletop) [DOCUMENTATION REQUIRED]
   AND
4. Documentation of ONE of the following:
   a. Flexion contracture > 20 degrees at the metacarpophalangeal (MP) joint
      OR
   b. Flexion contracture > 20 degrees at the proximal interphalangeal (PIP) joint
   Molina Reviewer Note: Patients in clinical trials must have had a finger flexion contracture with a palpable cord of at least one finger (other than the thumb) of 20° to 100° in a metacarpophalangeal joint or 20° to 80° in a proximal interphalangeal (PIP) joint.
   AND
5. Prescriber attests, or clinical reviewer has found, that member has not received ANY of the following treatments:
   a. A surgical treatment (e.g., fasciectomy, fasciotomy) on the selected primary joint within 90 days before the first injection requested
      AND
   b. An anticoagulation medication (except for up to 150 mg/day of aspirin) within 7 days before the first injection
   AND
6. Documentation of functional impairment as a result of the contracture
   AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Xiaflex (collagenase clostridium histolyticum) include: History of hypersensitivity to Xiaflex or to collagenase used in other therapeutic applications]

CONTINUATION OF THERAPY:

A. PEYRONIE'S DISEASE:

1. Documented response to last treatment demonstrated by curvature improvement BUT curvature remains greater than 15 degrees (after most recent treatment cycle) [DOCUMENTATION REQUIRED of progress of all previous treatment cycles]
   NOTE: If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if further treatment is no longer clinically necessary, then subsequent treatment cycles are not considered medically necessary.
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. DUPUYTREN'S CONTRACTURE:

1. Reauthorization request is for treatment of a previously treated cord following recurrence (i.e., cord was successfully treated [contracture ≤5 degrees] 30 days after last injection, and contracture worsened relative by 20 degrees or more)
   NOTE: Continuation of therapy criteria is for the same treated cord. If the condition develops in a different cord, a new request must be submitted and meet all Initial Coverage criteria.
   AND
2. Documentation continued need for treatment has been formally assessed
   AND
3. Documentation member received less than 3 injections total in affected cord (at approximately 4-week intervals)
   AND
4. Documentation member followed up within 24 hours following an injection for finger extension procedure if a contracture persists (in order to qualify for additional injections)
   AND
6. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Peyronie's Disease:

Initial authorization: 6 weeks [One treatment cycle (2 Xiaflex injections and one penile modeling procedure per cycle)]

Continuation of Therapy: 18 weeks [Up to 3 additional treatment cycles (6 Xiaflex injections and 3 penile modeling procedures per cycle)]

Dupuytren's Contracture:

Initial authorization: 30 days [One injection]

Continuation of Therapy: 60 days [Up to 2 additional injections per cord (at approximately 4-week intervals)]

MOLINA REVIEWER NOTE: For New York Medicaid, please see appendix.

PRESCRIBER REQUIREMENTS:

Peyronie's Disease: Prescribed by or in consultation with a board-certified urologist or specialist in the treatment of male urological diseases [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

Dupuytren's Contracture: Prescribed by or in consultation with a board-certified healthcare provider experienced in injection procedures of the hand and in the treatment of DC [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:
Peyronie's Disease: One treatment cycle (2 Xiaflex injections and one penile modeling procedure per cycle) every 6 weeks up to 4 total treatment cycles
Total authorization: ONE course of treatment per plaque; consists of a maximum of 4 treatment cycles (2 Xiaflex injections and one penile modeling procedure per cycle); total of 8 injection procedures and 4 modeling procedures.

Dupuytren's Contracture: 0.58 mg intralesionally per cord up to three injections (days 0, 30, 60)
Total authorization: Maximum of THREE injections per cord AND ONE injection per 30 days for a total duration of therapy of 3 months (12 weeks)

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intralesional injection

DRUG CLASS:
Enzyme

FDA-APPROVED USES:
Indicated for:

- The treatment of adult patients with Dupuytren's contracture with a palpable cord
- The 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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Medicaid
New York (Source: New York State, Department of Health)
The Laws of New York Consolidated Laws of New York Chapter 55 Social Services Article 5 Title 11 Section 365-A "4. Any inconsistent provision of law notwithstanding, medical assistance shall not include, unless required by federal law and regulation as a condition of qualifying for federal financial participation in the medicaid program, the following items of care, services and supplies:…(e) drugs, procedures and supplies for the treatment of erectile dysfunction when provided to, or prescribed for use by, a person who is required to register as a sex offender pursuant to article six-C of the correction law,…(f) drugs for the treatment of sexual or erectile dysfunction, unless such drugs are used to treat a condition, other than sexual or erectile dysfunction, for which the drugs have been approved by the federal food and drug administration."
MUST check the Erectile Dysfunction Verification System (EDVS) for each request to determine member's

sex offender status. IF a member is on the sex offender list the request must be forwarded to the medical director AND provider must provide the rationale for prescribing and note the reason(s) why alternative treatment options are inappropriate to treat the enrollee's health condition. Before issuing an adverse determination, the Medical Director must make reasonable attempts to engage in a peer–to–peer discussion with the requesting provider to understand the reasons behind the need for prescribing the requested drug. The Medical Director may extend the review time, if requested by the provider or patient, or if such extension is in the best interest of the patient's health condition.
For after-hours, holiday, and weekend pharmacy requests Molina Healthcare, Inc. can authorize a seventy-two (72) hour emergency supply of the requested product and must note within the authorization file that the drug is prescribed to treat a condition other than sexual or erectile dysfunction and that the drug has been approved by the FDA to treat that condition. The case must still be sent to the Medical director for checking the EDVS status of the member, as soon as possible on the next business day.
MOLINA REVIEWER NOTE: For any member on the sex offender list, approval can only be for 30 days per authorization

Appendix 1:
Collagen: A fibrous protein found in connective tissue, bone, and cartilage.
Collagenase: An enzyme capable of causing the hydrolysis of collagen and gelatin
Contracture: Shortening of the tendon or muscle because of intrinsic or extrinsic conditions.
Fascia: A sheet of fibrous tissue that envelops the body beneath the skin; it also encloses muscles and groups of muscles and separates their several layers or groups.
Fasciectomy: Surgical removal of the fibrous tissue beneath the skin.
Fibroproliferative: Producing new fibrous tissue.
Metacarpophalangeal (MP) joint: Commonly referred to as the knuckle; attached to the proximal first phalanges.
Proximal interphalangeal (PIP) joint: The second joint of the finger

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Peyronie Disease: The FDA approval of Xiaflex for PD was based on two multicenter, randomized, double-blind, placebo- controlled phase 3 studies in 832 adult males (n=832) in the pivotal IMPRESS I and IMPRESS II trials.

IMPRESS (Investigation for Maximal Peyronie Reduction Efficacy and Safety Studies; IMPRESS I and II) examined collagenase injections in 417 and 415 participants (n=832), respectively, through a maximum of 4 treatment cycles, each separated by 6 weeks (for up to 8 injections of 0.58 mg collagenase). The duration of each study was 52 weeks. The studies evaluated the safety and effectiveness of CCH intralesional injections administered twice per treatment cycle for up to 4 treatment cycles in men with PD. Patients had a penile curvature deformity of at least 30 degrees in the stable phase of PD and stratified by baseline penile curvature (30 to 60 vs. 61 to 90 degrees). Patients were randomized 2:1 to receive either CCH (0.58 mg) or placebo injections plus penile remodeling. The trial did not enroll patients with ventral curvature deformity, isolated hourglass deformity, or a calcified plaque that may interfere with injection technique. Patients were randomized in a 2:1 ratio to receive up to four cycles (eight injections) of Xiaflex or placebo and were followed for weeks 24-52. Each treatment cycle consisted of 2 Xiaflex injections administered 1 to 3 days apart, followed by a penile modeling procedure 1 to 3 days after the second injection of the treatment cycle. Treatment cycles were repeated at approximately 6-week intervals for a maximum of 3 cycles. Patients were advised to perform penile modeling procedures at home for 6 weeks after each treatment cycle. Up to 4 total modelling procedures were performed. Two co-primary end points measured the change from baseline to week 52 of penile curvature deformity and Peyronie Disease Bother Domain (PDBD) Score from the Peyronie Disease Questionnaire (PDQ). Data from the IMPRESS I and II studies were combined, and men treated with collagenase injections showed a mean percent improvement in penile curvature abnormality of 34%, compared to 18% improvement in penile curvature in the placebo group; this change in curvature and the percent improvement in the collagenase group were significantly greater than in the placebo group. The majority of Xiaflex-treated men and those who received placebo (92% and 61%, respectively) experienced

at least 1 adverse reaction. Most AEs were local events of the penis and groin and the majority were of mild or moderate severity. Of these events, 79% resolved without intervention within 14 days of the injection. The most frequently reported complications (≥ 45%) in the collagenase-treated group included penile ecchymosis, penile swelling and penile pain. 6 participants experienced treatment- related serious adverse events (including corporeal rupture in 3 cases and penile hematoma in the other 3 cases).

Russell et al. conducted a systematic review of plaque injection therapy for PD, which included two studies of collagenase. Both articles reported positive treatment outcomes. One study was rated according to the Oxford Centre for Evidence-Based Medicine criteria as level 2 (RCT with low power or <80% follow-up/retention or good-quality, randomized prospective cohort study) and the other level 4 (case series or poor-quality cohort or case-control study).

National and Specialty Organizations

The **American Urological Association** (AUA 2015) published a guideline addressing the treatment of PD:

- AUA guidelines recommend oral NSAIDs for pain associated with PD. AUA states that oral vitamin E, tamoxifen, procarbazine, omega-3 fatty acids, or a combination of vitamin E with L- carnitine is not recommended to be utilized in stable PD.
- Intralesional collagenase with clinician/patient modeling is recommended in individuals stable PD, a curvature >30 and <90 degrees, and when the patient has intact erectile function (regardless of whether medications are needed to obtain erection or not).
- Clinicians may administer intralesional CCH in combination with modeling by the clinician and by the patient for the reduction of penile curvature in patients with stable PD, penile curvature > 30 and < 90, and intact erectile function (with or without the use of medications). This recommendation is based on the findings of the IMPRESS studies and was given a "Moderate Recommendation" with an "Evidence Strength Grade B," indicating moderate quality evidence and moderate certainty.

Dupuytren's Contracture: FDA approval of CCH for the management of Dupuytren contracture was based on the results of CORD I and CORD I Extension, multicenter, randomized, double-blind, placebo- controlled trials (n=374).

Hurst et al. (2009) conducted a double-blind, placebo-controlled, multicenter trial of 308 subjects with Dupuytren's joint contractures of 20 degrees or more to receive up to 3 injections of CCH (n=204) or placebo (n=104) in the contracted collagen cord at 30-day intervals, with manipulation of the joints the day following injection. Joints were stratified according to joint type (MP or PIP) and the joints were manipulated one day after injection if necessary. The mean number of affected joints was 3. The proportion of patients who had undergone prior surgery for DC was 38%, with 8% having had surgery for contracture on the same finger as the primary treated joint. Findings included a reduction in contractures to less than 5º in 64% of collagenase-injected patients compared with 6.8% of patients treated with placebo. Patients with MCP involvement tended to improve to a greater extent, as did those patients with less severe flexion contractures. The mean range of motion in the treated joints also improved significantly (from 44 to 81 degrees versus 45 to 50 degrees). Response rates were better in patients with less severe contractures (Hurst et al. CORD I Study Group).

Study 2 enrolled 66 patients (n=66). The mean number of affected joints was 3.3. The proportion of patients who had undergone prior surgery for DC was 53%, with 18% having had surgery for contracture on the same finger as the primary treated joint. More collagenase-treated joints achieved a reduction in contracture and a greater increase in range of motion of the affected joints.

Peimer et al. (2015) analyzed the recurrence rate of DC 5 years after successful treatment with CCH (CORDLESS study) in a non-interventional follow-up in patients from previous CCH clinical studies. Successfully treated joints was defined as joint correction 5° contracture or less following CCH treatment (prospectively established definition of success by Hurst et al.). The aim of this study was to evaluate the long-term durability of CCH treatment across multiple studies that used this definition of success. Recurrence was defined as 20° or greater worsening (relative to day 30 after the last injection) with a palpable cord or

any medical/surgical intervention to correct new/worsening contracture. The study enrolled patients (n=644) with a total of 1,081 treated joints evaluated annually for contracture and safety at 2, 3, 4, and 5 years after their first injection (0.58 mg) of CCH. A total of 1,081 treated joints with more than one follow-up were analyzed; of these, 623 joints (58%) were initially treated successfully (i.e., reduction of contracture to 0° to 5°). The follow-up study concluded that longer-term (>5 years) follow-up in 1,081 joints treated with collagenase demonstrated an overall recurrence rate of 47% in both metacarpophalangeal and proximal interphalangeal joints combined. This rate (47%) is comparable with the published recurrence rates after surgical treatments, with one reported long-term treatment-related adverse event. The recurrence rate was worse at the PIP joint (66%) than the MCP joint (39%), which parallels results seen with needle aponeurotomy and open surgery (Peimer et al. 2015).

Xiaflex REMS Program

Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease, XIAFLEX is available only through the XIAFLEX REMS Program.
Required components of the XIAFLEX REMS Program include the following:
• Prescribers must be certified with the program by enrolling and completing training in the administration of XIAFLEX treatment for Peyronie's disease.
• Healthcare sites must be certified with the program and ensure that XIAFLEX is only dispensed for use by certified prescribers.
Further information is available at www.XIAFLEXREMS.com or 1-877-313-1235.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Xiaflex (collagenase clostridium histolyticum) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Xiaflex (collagenase clostridium histolyticum) include: Peyronie's plaques that involve the penile urethra and a history of hypersensitivity to Xiaflex or to collagenase used in other therapeutic applications.

OTHER SPECIAL CONSIDERATIONS:
Xiaflex (collagenase clostridium histolyticum) has a Black Box Warning for corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg

AVAILABLE DOSAGE FORMS:
Xiaflex SOLR 0.9MG single-use vial

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Appendix	Q4 2025

REVISION- Notable revisions: Coding/Billing Information Template Update ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Quantity Drug Class Appendix Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms	Q4 2023
MCP Conversion	Q4 2022
Policy reviewed. Updated references. No changes to medical necessity criteria. Updates to policy in Continuation of Therapy' section: Removal of criterion for 'Member currently meets ALL initial coverage criteria' and 'Compliance' criteria since not applicable to policy (states 'Not Applicable')	6/9/2021
Policy reviewed and updated, no changes in coverage criteria, updated references	Q3 2020
Policy reviewed and updated, no changes in coverage criteria, updated references	Q4 2019
Policy reviewed and updated, no changes in coverage criteria, updated references	7/10/2018
Policy reviewed and updated, no changes in coverage criteria, updated references.	9/19/2017
Policy reviewed and updated, no changes in coverage criteria, updated references.	12/15/2016
New policy. Internal Peer Review. MCPC Chair, Sr. Medical Director of Policy and Medical Directors	7/27/2016