

**UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM**

**CONTAINS CONFIDENTIAL PATIENT INFORMATION**

**Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538**

<input type="checkbox"/> <b>Initial Request</b> <input type="checkbox"/> <b>Renewal</b> <input type="checkbox"/> <b>Appeal/Redetermination<sup>1</sup></b>																								
<input type="checkbox"/> <b>Urgent<sup>2</sup></b> <input type="checkbox"/> <b>Non-Urgent</b>																								
<b>Requested Drug Name: Xiaflex® (collagenase clostridium histolyticum) – Commercial and Medicare Part B Prior Authorization Form</b>																								
<b>Patient Information:</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>Patient Name:</td></tr> <tr><td>Member/Subscriber Number:</td></tr> <tr><td>Policy/Group Number:</td></tr> <tr><td>Patient Date of Birth (MM/DD/YYYY):</td></tr> <tr><td>Patient Address:</td></tr> <tr><td>Patient Phone:</td></tr> <tr><td>Patient Email Address:</td></tr> <tr><td> </td></tr> <tr><td>Prescription Date:</td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </table>	Patient Name:	Member/Subscriber Number:	Policy/Group Number:	Patient Date of Birth (MM/DD/YYYY):	Patient Address:	Patient Phone:	Patient Email Address:		Prescription Date:			<b>Prescribing Provider Information:</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>Prescriber Name:</td></tr> <tr><td>Prescriber Fax:</td></tr> <tr><td>Prescriber Phone:</td></tr> <tr><td>Prescriber Pager:</td></tr> <tr><td>Prescriber Address:</td></tr> <tr><td> </td></tr> <tr><td>Prescriber Office Contact:</td></tr> <tr><td>Prescriber NPI:</td></tr> <tr><td>Prescriber DEA:</td></tr> <tr><td>Prescriber Tax ID:</td></tr> <tr><td>Specialty/Facility Name (If applicable):</td></tr> <tr><td>Prescriber Email Address:</td></tr> </table>	Prescriber Name:	Prescriber Fax:	Prescriber Phone:	Prescriber Pager:	Prescriber Address:		Prescriber Office Contact:	Prescriber NPI:	Prescriber DEA:	Prescriber Tax ID:	Specialty/Facility Name (If applicable):	Prescriber Email Address:
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<b>Prior Authorization Request for Drug Benefit:</b>																								
Patient Diagnosis and ICD Diagnostic Code(s):																								
Drug(s) Requested (with J-Code, if applicable):																								
Strength/Route/Frequency:																								
Unit/Volume of Named Drug(s):																								
Start Date and Length of Therapy:																								
Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:																								
Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:																								
<b>Xiaflex® (collagenase clostridium histolyticum)</b>  <b>Diagnosis (documentation supportive of diagnosis is required)</b> <input type="checkbox"/> Adult patient with Dupuytren's contracture <input type="checkbox"/> Adult male with Peyronie's disease <input type="checkbox"/> Other (please state): _____																								

**Clinical Consideration (for approval, please indicate and provide documentation of the following):**

**Diagnosis of Dupuytren's Contracture**

- Finger flexion contracture, with a *palpable chord* of at least one finger (other than the thumb), of greater than 20° in a metacarpophalangeal (MP) or a proximal interphalangeal (PIP) joint
- Physician has completed the Xiaflex REMS training (required)
- For the indication of Dupuytren's contracture, use Caremark Specialty Pharmacy

*When criteria are met, approval is given for 3 months to allow up to 3 injections at ~ 4 week intervals.*

**Diagnosis of Peyronie's Disease (INITIAL request):**

- Penile curvature deformity of  $\geq 30$  degrees **AND**
- Palpable plaque
- Physician has completed the Xiaflex REMS training (required)
- For the indication of Peyronie's, Xiaflex must be bought and billed via [www.besse.com](http://www.besse.com).

**Diagnosis of Peyronie's Disease (RENEWAL request up to a maximum of 4 cycles):**

- Penile curvature deformity is  $\geq 15$  degrees

*Note: If curvature deformity is < 15 degrees after the first, second or third cycle, no further treatment is warranted.*

*When criteria are met, approval is given in 1 cycle increments (equals 2 injections separated by 1-3 days). Up to a maximum of 4 cycles will be approved. Each cycle is separated by ~ 6 weeks.*

**Physician Specialty**

- General Surgeon
- Hand Surgeon
- Rheumatologist
- Plastic Surgeon
- Orthopedic surgeon
- Urologist (for Peyronie's Disease)
- Other: \_\_\_\_\_

**Coverage Policy:**

**Dupuytren's Contracture:** Our guideline for collagenase clostridium histolyticum (Xiaflex) requires a diagnosis of Dupuytren's Contracture. Documentation of finger flexion contracture, with a *palpable chord* of at least one finger (other than the thumb), of greater than 20° in a metacarpophalangeal (MP) or a proximal interphalangeal (PIP) joint is required. Provider Specialty required: General Surgeon, Hand Surgeon, Rheumatologist, Plastic Surgeon or Orthopedic Surgeon who has completed the Xiaflex REMS training. Specialty Pharmacy Provider required: Caremark Specialty Pharmacy

**Peyronie's Disease (INITIAL requests):** Our guideline for collagenase clostridium histolyticum (Xiaflex) requires a diagnosis of Peyronie's Disease. Documentation of penile curvature deformity of  $\geq 30$  degrees and palpable plaque is required. Provider Specialty required: Urologist who has completed the Xiaflex REMS training. For the indication of Peyronie's, Xiaflex must be bought and billed via [www.besse.com](http://www.besse.com).

**Peyronie's Disease (RENEWAL requests):** Our guideline for collagenase clostridium histolyticum (Xiaflex) requires a diagnosis of Peyronie's Disease. Documentation of penile curvature deformity of Penile curvature deformity is  $\geq 15$  degrees. Provider Specialty required: Urologist who has completed the Xiaflex REMS training. For the indication of Peyronie's, Xiaflex must be bought and billed via [www.besse.com](http://www.besse.com).

For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: <input type="checkbox"/> Patient's Home <input type="checkbox"/> Physician Office		Other:
<b>Prescriber or Authorized Signature:</b>		<b>Date:</b>
Dispensing Pharmacy Name and Phone Number:		

**Approved**

**Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.
2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

# Xiaflex® (collagenase clostridium histolyticum)

## CLASSIFICATION

- Connective Tissue Agent
- Enzyme

## DESCRIPTION

- Xiaflex consists of 2 microbial collagenases (AUX-I and AUX-II) that synergistically hydrolyze collagen resulting in lysis of collagen deposits and may result in enzymatic disruption of the cord in patients with Dupuytren contracture and in the plaque associated with Peyronie disease.
- Xiaflex is indicated for the treatment of adults with Dupuytren contracture with a palpable cord and for treatment of Peyronie disease in adult men with a palpable plaque and curvature deformity of at least 30 degrees at initiation of therapy.
- Clinical trial data for Dupuytren contracture: Contractures were released to 0 to 5 degrees of full extension after 3 injections of Xiaflex in 44% to 64% of patients with metacarpophalangeal (MP) or proximal interphalangeal (PIP) contractures, compared with 5% to 6.8% who received placebo, in 1 study (N=308). Contracture release was reached after just 1 injection in 27% to 39% of those receiving Xiaflex compared with 1% to 5% placebo in another study (N=66). The probability of remaining recurrence-free at 5 years after successful treatment was about 50% in a long-term follow-up study (N=645). Retreatment using up to 3 injections in patients with recurrent contractures (N=52) was clinically successful in 65% of MP joints and in 45% of PIP joints.
- Clinical trial data for Peyronie disease: Xiaflex was superior to placebo for the treatment of Peyronie disease in 2 multicenter, randomized, double-blind, controlled trials (n=832). Adult men with penile curvature deformity of a minimum of 30 degrees in a stable phase of Peyronie disease were eligible. Patients with ventral curvature deformity, isolated hourglass deformity, or a calcified plaque that may interfere with injection technique were excluded. Patients were randomized in a 2:1 ratio to receive up to 4 treatment cycles of Xiaflex or placebo. Each treatment cycle consisted of 2 study drug 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. The coprimary endpoints were percent change in penial curvature deformity and the change in Peyronie Disease Bother Domain (PDBD) Score from the Peyronie Disease Questionnaire (PDQ) from baseline to week 52. Intent to treat analysis showed: at week 52 in study 1, the mean change in penial curvature deformity from baseline was -35% in the Xiaflex arm (n=199) compared with -17.8% in the placebo arm (n=104; difference, -17.2%; 95% CI, -26.7% to -7.6%; p < 0.01). Additionally, at week 52 in study 1, the mean change in the PDBD score from baseline was -2.8 in the Xiaflex arm and -1.6 in the placebo arm (difference, -1.2; 95% CI, -2.4 to -0.03; p < 0.05). Similarly, at week 52 in study 2, the mean change in penial curvature deformity from baseline was -33.2% in the Xiaflex arm (n=202) compared with -21.8% in the placebo arm (n=107; difference, -11.4%; 95% CI, -19.5% to -3.3%; p < 0.01). Additionally, at week 52 in study 2, the mean change in the PDBD score from baseline was -2.6 in the Xiaflex arm compared with -1.5 in

the placebo arm (difference, -1.1; 95% CI, -2.1 to -0.002;  $p < 0.05$ ). Improvement in penile curvature deformity and in PDBD score in both studies was numerically similar among the subgroups stratified by baseline degree of curvature deformity. No clinically relevant differences in the coprimary endpoints were observed on the basis of erectile dysfunction severity and phosphodiesterase type 5 inhibitor use at baseline.

- Xiaflex has Orphan drug designation for treatment of Peyronie disease and treatment of advanced (involutional or residual stage) Dupuytren disease.
- Supplied as a single-use glass vials containing 0.9 mg of collagenase clostridium histolyticum as a sterile, lyophilized powder for reconstitution. Sterile diluent for reconstitution is also provided in a single-use glass vial.
- The most common adverse reactions when used for Dupuytren’s Contracture were edema peripheral (e.g., swelling of the injected hand), contusion, injection site hemorrhage, injection site reaction, and pain in the injected extremity.
- The most frequently reported adverse drug reactions when used for Peyronie’s Disease were penile hematoma, penile swelling and penile pain.
- There is a XIAFLEX REMS Program that requires prescribers be certified with the program by enrolling and completing training in the administration of XIAFLEX treatment. Healthcare sites must also be certified with the program and ensure that XIAFLEX is only dispensed for use by certified prescribers when used for Peyronie’s disease. Further information is available at [www.XIAFLEXREMS.com](http://www.XIAFLEXREMS.com) or 1-877-313-1235.

## FORMULARY COVERAGE

Prior authorization: Required  
 Good Health Formulary: Tier 6  
 Commercial Formulary: Tier 6  
 Medicare Part B coverage: Medical Benefit

## COVERAGE CRITERIA

Xiaflex® (collagenase clostridium histolyticum) meets the definition of **medical necessity** for all FDA approved indications, not otherwise excluded from Part B. Xiaflex® is considered **experimental** when used for any condition or diagnosis not FDA approved.

### Dupuytren’s contracture with a palpable cord

Clinical Criteria meeting Approval (approve if all of the following apply)	Clinical Criteria meeting Denial (deny if any of the following apply)
Adult 18 years of age or older	Younger than 18 years
Diagnosis is Dupuytren’s Contracture	Any other diagnosis
Patient has finger flexion contracture, with a <i>palpable chord</i> of at least one finger (other than the thumb), of greater than 20° in a metacarpophalangeal (MP) or a proximal interphalangeal (PIP) joint	No palpable cord. AND/OR Flexion contracture of the thumb AND/OR Less than 20° angle in MP
Physician is Xiaflex REMS Certified (required)	Physician has NOT completed REMS/is not certified.

When criteria are met, approval is given for 3 months to allow up to 3 injections at ~ 4 week intervals.

### Treatment of adult men with Peyronie’s disease

Clinical Criteria meeting Approval (approve if all of the following apply)	Clinical Criteria meeting Denial (deny if any of the following apply)
Adult 18 years of age or older	Younger than 18 years
Diagnosis is Peyronie’s disease	Any other diagnosis
Patient has <i>palpable plaque</i> at start of therapy Patient has curvature deformity of $\geq 30^\circ$ at the start of therapy.	Patient does not have a palpable plaque AND/OR Patient curvature deformity is $<30^\circ$
Physician is Xiaflex REMS Certified (required)	Physician has NOT completed REMS/is not certified.
<b>RENEWAL request up to a maximum of 4 cycle:</b> Penile curvature deformity is $\geq 15$ degrees <i>Note: If curvature deformity is <math>&lt; 15</math> degrees after the first, second or third cycle, no further treatment is warranted.</i>	RENEWAL: Curvature deformity is $< 15$ degrees after the first, second or third cycle

When criteria are met, approval is given in 1 cycle increments (equals 2 injections separated by 1-3 days). Up to a maximum of 4 cycles will be approved. Each cycle is separated by ~ 6 weeks.

#### Required Provider Specialty:

- Note: Injection of collagenase clostridium histolyticum in the treatment of Dupuytren contracture or for the treatment of Peyronie disease is limited to those healthcare providers who are experienced in injection procedures and treatment of the respective conditions. Injection of collagenase clostridium histolyticum for the treatment of Peyronie disease is restricted to those healthcare providers who have completed required training.
- For Dupuytren contracture approval is limited to: General Surgeon, Hand Surgeon, Rheumatologist, Plastic Surgeon, Orthopedic surgeon
- For Peyronie’s Disease approval is limited to: Urologist who is Xiaflex REMS certified

#### Specialty Pharmacy Provider:

- For the indication of Dupuytren’s contracture, the procurement of this drug must be through Caremark Specialty Pharmacy (CVS). CVS cannot dispense this drug if the indication is Peyronie’s disease due to enforced REMS program by FDA for Xiaflex for Peyronie’s disease.
- For the indication of Peyronie’s, Xiaflex must be bought and billed via [www.besse.com](http://www.besse.com).

## DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patients less than 18 years):

- Dupuytren contracture of a metacarpophalangeal or proximal interphalangeal joint:** inject 0.58 mg INTRALESIONALLY into a palpable cord; if contracture persists after 24 to 72 hours, perform a finger extension procedure to facilitate cord disruption; if contracture remains after 4 weeks, may reinject with a single dose of 0.58 mg INTRALESIONALLY followed by finger extension procedure 24 to 72 hours later; may perform up to 3 injection and finger extension procedures per cord at 4-week intervals; may perform 2 injections in same hand per visit. Inject only 1 cord at a time. For patients with multiple metacarpophalangeal or proximal interphalangeal contractures, inject cords in a sequential order.

- **Peyronie's Disease:** inject 0.58 mg INTRALESIONALLY into the Peyronie plaque. If more than 1 plaque is evident, inject into the plaque causing the deformity. A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of 2 injections separated by 1 to 3 days and 1 penile modeling procedure performed 1 to 3 days after the second injection. The interval between treatment cycles is approximately 6 weeks. If after the first, second, or third treatment cycle, the curvature deformity is less than 15 degrees or if additional treatment cycles are not clinically necessary, subsequent treatment cycles should not be administered. The safety of more than 1 treatment course is not known.

## PRECAUTIONS

### Black Box Warning:

- Corporal rupture (penile fracture) and severe penile hematoma have been reported with use. Promptly evaluate signs or symptoms that reflect serious penile injury, as surgical intervention may be required. Collagenase clostridium histolyticum is only available through a restricted program called the Xiaflex REMS program.

### Contraindications:

- Hypersensitivity to collagenase clostridium histolyticum or to collagenase used in any therapeutic application.
- Peyronie plaques involving the penile urethra.

### Precautions:

- Concomitant use:
  - Avoid concomitant use of anticoagulants (except for low-dose aspirin).
- Hematologic:
  - Avoid use in patients with coagulation disorders.
  - Bleeding events including ecchymosis, contusion, hematoma, and injection site hemorrhage have been reported.
- Immunologic:
  - Hypersensitivity reactions including anaphylaxis have been reported.
  - IgE-antidrug antibodies may develop.
- Musculoskeletal:
  - Avoid injecting drug into tendons, nerves, blood vessels, and other collagen-containing structures.
  - Flexor tendon ruptures (including permanent injuries), have been reported. There is increased risk with injection into collagen-containing structure (i.e., tendons or ligaments).
  - Serious local reactions in the finger or hand have been reported including pulley rupture, ligament injury, complex regional pain syndrome, sensory abnormality of the hand, and skin laceration. Monitoring is recommended and surgical intervention may be required.
- Reproductive:
  - Inject drug only into the Peyronie's plaque. Avoid injection into urethra, nerves, blood vessels, corpora cavernosa, and other collagen-containing structures.
  - Increased risk of penile injury with injection into collagen-containing structures.

## Billing/Coding information

### CPT Coding:

20527	Injection, enzyme (e.g., collagenase), palmar fascial cord (i.e., Dupuytren's contracture)
26341	Manipulation, palmar fascial cord (i.e., Dupuytren's cord), post enzyme injection (e.g., collagenase), single cord

### HCPCS Coding:

J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg (For billing prior to 1/1/11 use J3590 or C9266)

## COST

- AWP (September 2010) – Xiaflex 0.9mg vial for injection (1): \$3,900.00
- AWP (February 2013) – Xiaflex 0.9mg vial for injection (1): \$3,997.50

## COMMITTEE APPROVAL

- January 2011

## GUIDELINE UPDATE INFORMATION

September 2010	Medical Policy created
February 2016	Medical Policy updated

## REFERENCES

- DRUGDEX®, accessed 2/20/2016.
- Product Information: Xiaflex® (collagenase clostridium histolyticum), solution for injection, for intralesional use. Auxilium Pharmaceuticals, Inc., Malvern, PA, 2015.