



Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Adult patient with Dupuytren's contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint of the hand	<input type="checkbox"/> Other (please state): _____ _____ _____
Clinical Consideration	<input type="checkbox"/> Finger flexion contracture with a palpable chord of at least one finger (other than the thumb) of greater than 20° in a MP or PIP joint	
Physician Specialty	<input type="checkbox"/> General Surgeon <input type="checkbox"/> Hand Surgeon <input type="checkbox"/> Rheumatologist <input type="checkbox"/> Plastic Surgeon <input type="checkbox"/> Orthopedic surgeon	<input type="checkbox"/> Physician has completed the Xiaflex Xperience training (required)
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Xiaflex [®] (collagenase clostridium histolyticum) Strength _____ Sig _____ Qty _____ Refills _____	
	<p><i>*Please attach all relevant medical records and test results*</i></p> <p>We will not process incomplete forms.</p> <p>If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete.
 (please sign and date)

 Prescriber Signature

 Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____

Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 11/07/11

RMHP Formulary Coverage Policy

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

Xiaflex (collagenase, clostridium histolyticum)

CLASSIFICATION

- Proteolytic enzyme

DESCRIPTION

- Xiaflex is a collagenase enzyme that hydrolyzes collagen resulting in lysis of collagen deposits
- Xiaflex is indicated for the treatment of Dupuytren's contracture with a palpable cord, a condition involving the connective tissue in the hands that leads to abnormal curvature/contracture of the fingers.
- A greater proportion of patients treated with collagenase clostridium histolyticum compared with placebo experienced reduced contractures of the metacarpophalangeal or proximal interphalangeal joint at 30 days post-injection in a multicenter, double-blind, randomized, placebo-controlled trial (n=308). Likewise, in 2 more multicenter, randomized, double-blind, placebo-controlled trials (n=374) more patients treated with collagenase clostridium histolyticum experienced a reduction in contracture of the metacarpophalangeal or proximal interphalangeal joints than with placebo
- To be included in the pivotal trials, patients 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 (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint
- Unapproved uses of collagenase, for which Xiaflex use is likely, include prolapsed lumbar intervertebral (herniated) disk and Peyronie's disease (abnormal curvature of the penis).
- Due to specific training requirements, TrailBlazer expects to see Xiaflex injection to be performed only by the following specialties: orthopedic surgeon, hand surgeon, general surgeon, plastic surgeon, or rheumatologist.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T6
Commercial Formulary:	T6
Medicare Part D coverage:	Part B, T5 if acquired at a pharmacy

COVERAGE CRITERIA

Xiaflex (collagenase, clostridium histolyticum) meets the definition of **medical necessity** for the following:

- Dupuytren's contracture, with a palpable cord
 - This is defined as a Finger flexion contracture with a palpable chord of at least one finger (other than the thumb) of greater than 20° in a MP or PIP joint

Xiaflex (collagenase, clostridium histolyticum) is considered **experimental** for the following:

- Any disorder not FDA approved, including herniated vertebral disk and Peyronie's disease

Required Provider Specialty:

- Orthopedic surgeon, hand surgeon, general surgeon, plastic surgeon or rheumatologist
- Completion of the Xiaflex Xperience training

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy have not been established in pediatric patients):

- Initial dose: 0.58 mg INTRALESIONALLY in 3 divided injections followed by finger extension procedure; if contracture remains re-inject with a single dose of 0.58 mg INTRALESIONALLY followed by finger extension procedure; MAX of 3 times per cord at 4-week intervals

PRECAUTIONS:

- Anaphylaxis could occur as IgE anti-drug antibodies have been documented
- Coagulation disorder, including concomitant anticoagulants (except low-dose aspirin); use with caution
- Flexor tendon rupture or ligament damage with permanent injury may occur; avoid injection into tendons, nerves, blood vessels, or collagen-containing structures of the hand
- Pulley rupture, complex regional pain syndrome (CRPS), and sensory abnormality of the hand may occur

Billing/Coding information

Associated HCPCS Codes:

C9266	Injection, collagenase clostridium histolyticum, 0.1mg
J3590	Unclassified biologics

Associated CPT Coding:

Associated ICD-9 Coding:

728.6	Contracture of palmar fascia (only expected covered use)
607.85	Peyronie's disease (not covered)

COST

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

COMMITTEE APPROVAL:

- January 26, 2011

GUIDELINE UPDATE INFORMATION:

Sept 2010	Policy created

REFERENCES:

- DRUGDEX®, accessed 09/14/2010
- Product Information: XIAFLEX(TM) intralesional injection, collagenase clostridium histolyticum intralesional injection. Auxilium Pharmaceuticals, Inc, Malvern, PA, 2010.
- <http://www.trailblazerhealth.com/Tools/Notices.aspx?DomainID=1&ID=13603>, accessed 1/11/2011.