



## Prior Authorization Approval Criteria

### *Xiaflex (collagenase clostridium histolyticum )*

<b>Generic name:</b>	collagenase clostridium histolyticum
<b>Brand name:</b>	Xiaflex
<b>Medication class:</b>	Enzyme
<b>FDA-approved uses:</b>	For the treatment of adult patients with Dupuytren's contracture with a palpable cord.
<b>Available dosage forms:</b>	single use, glass vials containing 0.9mg of collagenase clostridium histolyticum as a sterile, lyophilized powder.
<b>Usual dose:</b>	Inject 0.58mg of Xiaflex into a palpable Dupuytren's cord with a contracture of a metacarpophalangeal joint or a proximal interphalangeal joint according to the injection procedure. Approximately 24 hours following an injection, perform a finger extension procedure if a contracture persists. <b>Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.</b> Inject only one cord at a time. If a patient has other cords with contractures, inject each cord in sequential order.
<b>Approximate monthly cost:</b> (based on AWP 2010)	\$3900.00 for a 0.58mg dose in a 0.9mg single-use glass vial
<b>Duration of therapy:</b>	Depends upon response to treatment and number of cords affected. Can be up to a maximum of 3 sessions per cord at 4 week intervals.

#### **Criteria for use** *(bullet points below are all inclusive unless otherwise noted):*

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have Dupuytren's contracture with a palpable cord, functional impairment and fixed-flexion contractures of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more (excluding the thumb).
- Must be 18 years of age or older.
- Xiaflex should only be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. (orthopedic surgeon, hand surgeon, general surgeon, plastic surgeon, or rheumatologist)
- Upon request, documentation of credentials supporting fellowship training in procedures of the hand must be made available.
- Only one cord per session should be injected. If patient has other cords with contractures, treat each in sequential order.
- Must not have had surgery on the primary joint within the past 90 days.

#### **Criteria for continuation of therapy:**

- Injection may be repeated up to a maximum of 3 sessions per cord at 4 week intervals if reduction in primary joint contracture is not 0-5 degrees of full extension.
- Patient must follow-up within 24 hours following an injection for finger extension

- procedure if a contracture persists in order to qualify for more injections.
- If after the second injection there is no improvement the 3<sup>rd</sup> injection may not be approved.

**Contraindication:**

- None at this time.

**Not approved if:**

- Does not meet the above stated criteria.

**Special considerations:**

- Xiaflex will only be available through a managed distribution program called Xiaflex Experience Program.
- Medical benefit available through CVS/Caremark distribution.
- Current standard of care is surgery and the indications for surgery are similar to the indications for Xiaflex.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/08/10