

## Xiaflex® (collagenase clostridium histolyticum)

Last Review Date: December 30, 2020

Number: MG.MM.ME.cC5

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### Definitions

Xiaflex® (collagenase clostridium histolyticum) is a biologic injectable that enzymatically breaks down collagen when injected directly into a Dupuytren's cord. This can result in contracture reduction and range of motion improvement.

### Dosing

Max units (per dose and over time):

- Dupuytren's contracture:
  - 58 billable units per cord up to 3 times approximately 4 weeks apart
- Peyronie's Disease:
  - 58 billable units on each of 2 days 1-3 days apart every 6 weeks a maximum of 4 times

### Guideline

Xiaflex (collagenase clostridium histolyticum) is considered medically necessary for the following diagnosis when the subsequent criteria are met:

Dupuytren's Contracture:

- Patient is 18 years of age or older; **AND**
- Patient has a palpable cord; **AND**
- Patient's with recent onset disease with signs of inflammation (tenderness, nodules, or tenosynovitis) have had an ineffective trial with a corticosteroid injection; **AND**
- Patient presents with one of the following:
  - Considerable function impairment as demonstrated by documentation of flexion deformities >20 degrees at the MP or PIP joint; **OR**
  - Presence of flexion deformities (described above) and inflammation that has been refractory to steroid and hand therapy

**Peyronie's Disease:**

- Patient is 18 years of age or older; **AND**
- Patient has palpable plaque; **AND**
- Patient has a curvature deformity of at least 30 degrees at the start of therapy

Coverage for Xiaflex may be renewed for the following diagnosis when subsequent criteria are met:

**Peyronie's Disease:**

- Patient's curvature deformity is 15 degrees or greater

**Limitations/Exclusions**

- Approval will be granted for 12 weeks for a diagnosis of Dupuytren's Contracture per cord and may not be renewed
- Subsequent approvals for a diagnosis of Dupuytren's Contracture will require a new authorization
- Approval will be granted for 6 weeks for a diagnosis of Peyronie's Disease and may be renewed a maximum of 3 times
- As serious complications or damage may occur, Xiaflex should only be administered by a health care professional experienced with hand injections (for Dupuytren's contracture) or urologists (for Peyronie's disease) who have received certification in the Xiaflex Risk Evaluation and Mitigation Strategy (REMS) Program.

**Applicable Procedure Codes**

|       |  |
|-------|--|
| 20550 | Injection(s); single tendon sheath, or ligament, aponeurosis (e.g., plantar "fascia")                              |
| 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 |
| 29130 | Application of finger splint; static   |
| 54200 | Injection procedure for Peyronie disease;  |
| 54235 | Injection of corpora cavernosa with pharmacologic agent(s) (e.g., papaverine, phentolamine)                        |
| 96372 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular      |
| J0775 | Injection, collagenase, clostridium histolyticum, 0.01 mg  |

**Applicable Diagnosis Codes**

|       |   |
|-------|---|
| M72.0 | Palmar fascial fibromatosis [Dupuytren] |
| N48.6 | Induration penis plastica               |

**Review History**

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|------------|----------------------------------|
| 12/30/2020 | Annual review: no policy changes |
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**References**

XIAFLEX™

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1. Anderson, Bruce C, Sheon Robert P. Dupuytren's contracture. In: UpToDate, edited by Zacharia Isaac, published by UpToDate in Waltham, MA. 2010.
2. FDA. Xiaflex Prescribing Information. Revised October, 2019. Accessed December 2020.
3. Specialty-matched clinical peer review.