

Xiaflex®

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Definitions

Dupuytren's contracture	Affects the connective tissue found beneath the skin in the palm of the hand. The excess buildup of collagen causes the formation of thick rope-like cords of tissue that can prevent the fingers from being able to relax and straighten normally.
Peyronie's disease	Curvature deformity of the penis
Xiaflex® (collagenase clostridium histolyticum)	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 and administration

The drug is supplied as lyophilized powder that must be reconstituted with a diluent.

A. Dupuytren's contracture¹

1. Dosing — 0.58 mg (reconstituted) per injection into a palpable cord with contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint.
2. Administration
 - a. Initial cord injection.
 - b. Contracture persists at 24 hours post injection — finger extension procedure(s) performed.

¹ Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.

- c. Contracture persists at 4 weeks post injection — repeat injection. (Finger extension procedure[s] performed the following day if contracture remains).

B. Peyronie's Disease²

A treatment cycle consists of two XIAFLEX injection procedures and a penile modeling procedure.

1. Dosing — 0.58 mg into target area in Peyronie's plaque
2. Administration
 - a. Initial injection (post induction of penile erection through intracavernosal injection of 10 or 20 micrograms of alprostadil) once on each of two days; 1 to 3 days apart
 - b. Penile modeling procedure is performed 1 to 3 days post second injection of each treatment cycle.

Guideline

- A.** Dupuytren's Contracture — members (> 18 years of age) who have a palpable cord are eligible for coverage of Xiaflex when **either** of the following criteria is met:

1. Considerable functional impairment, as demonstrated by documentation of either of the following:
 - a. Flexion deformities > 20 degrees at the MP joint.
 - b. Flexion deformities > 20 degrees at the PIP joint.

OR

2. Presence of flexion deformities (as described in # 1) + inflammation that has been refractory to steroid and hand therapy.

A trial of corticosteroid injection must first be tried for those with recent disease onset who present with signs of inflammation (tenderness, nodules or tenosynovitis). If this is not effective, then collagenase therapy should follow.

- B.** Peyronie's Disease — adult male members with Peyronie's disease who have a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

Limitations/Exclusions

1. 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](#).
2. RE: Dupuytren's — g reater than 3 injections per cord are not considered medically necessary and will therefore not be covered.
3. RE: Peyronie;s Disease — If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles are not considered medically necessary and will therefore not be covered.

² For each plaque causing the curvature deformity, up to four treatment cycles may be administered. Each treatment cycle may be repeated at approximately six-week intervals.

Applicable Procedure Codes

20550	Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar "fascia")
20527	Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture)
26341	Manipulation, palmar fascial cord (ie, Dupuytren's cord), post-enzyme injection (eg, collagenase), single cord
29130	Application of finger splint; static
54200	Injection procedure for Peyronie disease;
54235	Injection of corpora cavernosa with pharmacologic agent(s) (eg, 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

References

Anderson, Bruce C, Sheon Robert P. Dupuytren's contracture. In: UpToDate, edited by Zacharia Isaac, published by UpToDate in Waltham, MA. 2010.

FDA. Xiaflex Prescribing Information. December 2016.

http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex_prescribing_information.html. Accessed June 6, 2016.

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