



Xiaflex Medical Policy

Drug(s) Applied:	Xiaflex (collagenase clostridium histolyticum)
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Medical Billing:

J0775	Xiaflex (Collagenase, clost hist inj))	1 unit = 0.01mg
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Initial Therapy Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication documented by clinical chart notes within the last 180 days and all the following criteria are met:

I. Peyronie's Disease

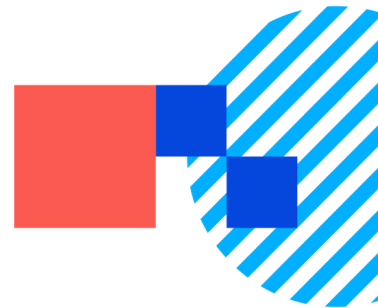
- Age 18 years or older **and**
- Curvature deformity of at least 30 degrees but less than 90 degrees prior to start of treatment **and**
- Palpable plaque present and plaque do not involve penile urethra **and**
- Stable Peyronie's disease without worsening curvature for at least 3 months **and**
- Administered by a healthcare provider experienced in the treatment of urological disease and who has completed the Xiaflex REMS program requirements.

Approval Duration: 3 months (up to 2 injections)

II. Dupuytren Contracture

- Age 18 years or older **and**
- Finger flexion contracture with a palpable cord present at metacarpophalangeal joint or proximal interphalangeal joint prior to start of treatment **and**
- Contracture is at least 20 degrees prior to start of treatment **and**
- Positive tabletop test **and**
- Has not received surgical treatment on the selected primary joint within the last 90 days **and**
- Prescribed by or in consultation with a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren contracture;

Approval Duration: 3 months (up to 2 injections)



Continued Therapy Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication documented by clinical chart notes within the last 180 days and all the following criteria are met:

III. Peyronie's Disease

- A. Curvature deformity is greater than 15 degrees after initial treatment **and**
- B. Penile modeling procedure was completed after Xiaflex injection **and**
- C. Maximum number of treatments cycles (1 cycle = 2 Xiaflex injections) does not exceed 4

Approval Duration: 3 months (up to 2 injections)

IV. Dupuytren's Contracture

- A. Last treatment was greater or equal to 4 weeks ago **and**
- B. Has not received more than three total injections per affected cord **and**
- C. Has not received surgical treatment on the selected primary joint within the last 90 days

Approval Duration: 3 months (up to 2 injections)

References:

1. Xiaflex [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2021.
2. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. J Urol. 2015;194(3):745-753.
3. Hurst LC, Badalamente MA, Hentz VR, et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med. 2009;361(10):968-979.

Policy Owned by:

Document History

Approval Date	Approved By	Notes
	P&T Committee	Initial criteria review
		Annual review with changes