

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Xiaflex (collagenase clostridium histolyticum)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Xiaflex (collagenase clostridium histolyticum)

### APPROVAL CRITERIA

Requests for injection of Xiaflex (collagenase clostridium histolyticum) may be approved for the following:

- I. Individual has a diagnosis of Dupuytren's contracture; **AND**
  - II. Product will be injected into a palpable palmar cord, which has been documented to impair the individual's functional activities and measures either:
    - A. 20 degrees or more at the metacarpophalangeal joint; **OR**
    - B. 20 degrees or more at the proximal interphalangeal joint;**AND**
  - III. The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals;
- OR**
- IV. Individual has a diagnosis of Peyronie's disease; **AND**
  - V. Disease is stable as defined by symptoms ( including but not limited to, penile curvature and pain) for at least 6 months (AUA); **AND**
  - VI. Penile curvature greater than or equal to 30 degrees and less than or equal to 90 degrees (AUA); **AND**
  - VII. Individual has intact erectile function with or without use of medications (AUA); **AND**
  - VIII. Individual has palpable penile plaque(s).

Requests for Xiaflex (collagenase clostridium histolyticum) may not be approved when the above criteria are not met and for all other indications.

**Note:** Xiaflex has a black box warning for corporal rupture (penile fracture) or other serious penile injury when administered for the treatment of Peyronie's disease. Due to the risks of

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply. CRX-ALL-0473-19

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corporal rupture and other serious penile injury, Xiaflex is only available for the treatment of Peyronie's disease through a restricted REMS program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the Xiaflex REMS website: <http://www.xiaflexrems.com>.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 22, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Nehra A, Alterowitz R, Culkin DJ, et al: American Urological Association Education and Research, Inc., Peyronie's Disease: AUA Guideline. J Urol. 2015; 194(3):745-753. Accessed: August 22, 2019.

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