

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Xiaflex (clostridial collagenase histolyticum)

CG-DRUG-27

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 time approval for both initial and subsequent injections

Medications
Xiaflex (clostridial collagenase histolyticum)

APPROVAL CRITERIA

Dupuytren's Contracture

Initial injection:

Initial injection of Xiaflex (clostridial collagenase histolyticum) may be approved for the following:

- I. Individual has a diagnosis of Dupuytren's contracture, when injected into a palpable palmar cord, which has been documented to impair the individual's functional activities and which measures either of the following:
 - A. 20 degrees or more at the metacarpophalangeal joint; or
 - B. 20 degrees or more at the proximal interphalangeal joint.

Subsequent injections:

- I. Subsequent injections of Xiaflex (clostridial collagenase histolyticum) may be approved for treating Dupuytren's contracture up to 2 additional times per cord (total 3 injections per cord) at approximately 4-week intervals.

Peyronie's Disease

- I. Xiaflex (clostridial collagenase histolyticum) injections may be approved for treating Peyronie's disease when **all** of the following criteria are met:
 - A. Individual has stable disease as defined by symptoms (that is, penile curvature and pain) for at least 6 months (AUA); **AND**
 - B. Individual's penile curvature greater than or equal to 30 degrees and less than or equal to 90 degrees (AUA); **AND**
 - C. Individual has intact erectile function with or without use of medications (AUA) ;

AND

 - D. Individual has palpable penile plaque(s).

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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-0132-18

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Xiaflex (clostridial collagenase histolyticum) **may not** be approved for:

- I. Repeat injection of a previously treated cord within one year of a prior course is considered not medically necessary for treating Dupuytren's contracture; **OR**
- II. Injections for diagnoses other than Dupuytren's contracture and Peyronie's disease; **OR.**
- III. When the above approval criteria are not met.

Black box warning: Corporal Rupture (Penile Fracture) or other serious penile injury in the treatment of Peyronie's disease.

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

1. Auxilium Pharmaceuticals. Long-term Observational Evaluation of Subjects Treated With AA4500 in Studies AUX-CC-854, AUX-CC-856, AUX-CC-857/AUX-CC-858 and AUX-CC-859. NLM Identifier: NCT00954746. Last Updated on June 15, 2016. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT00954746?term=xiaflex&rank=14>. Accessed on February 23, 2018.
2. Auxilium Pharmaceuticals. The Safety and Effectiveness of AA4500 in Subjects with Peyronie's Disease. NLM Identifier: NCT00755222. Last Updated on October 5, 2017. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT00755222?term=injectable+AND+clostridial+collagenase&rank=5>. Accessed on February 23, 2018.
3. Collagenase Clostridium Histolyticum Monograph. October 30, 2014. American Hospital Formulary Service®. Available at: <http://www.ahfsdruginformation.com/>. Accessed on February 23, 2018.
4. Collagenase Clostridium Histolyticum (systemic). In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated February 2, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on February 23, 2018.
5. Hatzimouratidis K, Eardley I, Giuliano F, et al. European Association of Urology (EAU) Guidelines on Penile Curvature. Eur Urol. 2012; 62(3):543-552.
6. 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.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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- U.S. Food and Drug Administration (FDA). Xiaflex (clostridial collagenase histolyticum) Prescribing information. August, 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125338s102lbl.pdf. Accessed on February 23, 2018.

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