



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 16, 2022

XIAFLEX® (collagenase clostridium histolyticum)

LENGTH OF AUTHORIZATION: Dupuytren's Contracture – 3 months
Peyronie's disease – 6 months

REVIEW CRITERIA:

- Patient must be \geq 18 years of age.
- Must have a documented diagnosis of one of the following:
Dupuytren's Contracture with a palpable cord
 - Treatment cycle is repeated no more than 3 times at 4-week intervals.
 - Must be prescribed by or in consultation with an orthopedist or hand specialist.

-OR-

Peyronie's Disease

- Patient must have a palpable plaque and curvature deformity of at least 30 degrees prior to the initiation of therapy.
- Plaques do not involve the penile urethra.
- Treatment cycle is repeated no more than 4 times at 6-week intervals.
- Must be prescribed by or in consultation with a urologist or related specialist.

Note: Xiaflex is not FDA approved to treat erectile dysfunction exclusively or for cosmetic purposes. Medicaid does not reimburse for these indications.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- **Dosage form:** 0.9 mg single dose vial available as a Single-Use Package or a Dual-Pack (2 single use packages)
- Because of the risks of corporal rupture or other serious penile injury, Xiaflex is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX REMS Program. More information is available at <https://www.xiaflexrems.com/> or call 1-877-313-1235.