

Division: Pharmacy Policy	Subject: 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 ≥ 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.