

Xiaflex® (collagenase clostridium histolyticum)



When requesting Xiaflex® (collagenase clostridium histolyticum), the individual requiring treatment must be diagnosed with the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indication(s)

- The treatment of adult patients with Dupuytren's contracture with palpable cord
- The treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

Approved Off-label Compendial use(s)

- None

Coverage Guidelines

Dupuytren's Contracture

The individual must meet **all** of the following criteria for approval:

- The patient is greater than or equal to 18 years of age
- At baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees
- The patient will not be treated with more than a total of three injections (maximum) per affected cord
- The drug is administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture

Approval duration: 3 months

Peyronie's Disease

The individual must meet **all** of the following criteria for approval:

- The patient is greater than or equal to 18 years of age
- The patient meets **ONE** of the following:
 - At baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees; **OR**
 - In a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees; **AND**
- The patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease

- The drug is being administered by a healthcare provider experienced in the treatment of male urological diseases

Approval duration: 6 months

Dosing Guidelines

- Dupuytren's contracture:
 - o The dose is 0.58 mg per injection into an affected cord with a maximum of two cords (1.16 mg) per treatment visit
- Peyronie's disease:
 - o The dose is up to a total of eight 0.58 mg injections with cycles being separated by at least 6 weeks from the previous.

References

1. Xiaflex® [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc; June 2018.
2. Brazzelli M, Cruickshank M, Tassie E, et al. Collagenase clostridium histolyticum for the treatment of Dupuytren's contracture: systematic review and economic evaluation. Southampton (UK): NIHR Journals Library; 2015 Oct. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK326596/>. Accessed on January 2, 2019.
3. Nehra A, Alterowitz R, Culkin D, et al. Peyronie's disease: AUA guideline. *J Urol*. 2015;194(3):745-753.