

Xiaflex® (collagenase clostridium histolyticum)

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

FDA-Approved Indications

- Xiaflex is indicated for the treatment of adult patients with Dupuytren's contracture with palpable cord.
- Xiaflex is indicated for 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.

Coverage Guidelines

Dupuytren's Contracture

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

- Has at least one palpable cord in the affected hand;
- At baseline (prior to initial injection of Xiaflex), had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint that is associated with the palpable cord, of at least 20 degrees;
- Will not be treated with more than a total of three injections (maximum) per affected cord as part of the current treatment course;
- Is 18 years of age or older;
- Xiaflex 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:

- Is 18 years of age or older;
- Has at least one palpable plaque in the penis;
- Has a penile curvature deformity of at least 30 degrees at baseline (prior to use of Xiaflex) or has a penile curvature deformity of at least 15 degrees with prior treatment with Xiaflex; Has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease;

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

Approval duration: 6 months

Dosing Recommendations

Dupuytren's contracture

The dose of Xiaflex is 0.58 mg per injection into an affected cord. A maximum of two cords may be injected per treatment visit. For each affected cord, subsequent doses are administered no sooner than 4 weeks following the previous Xiaflex injection up to a maximum of three injections per cord.

Peyronie's disease

The dose of Xiaflex is 0.58 mg per injection administered into a Peyronie's plaque. A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of two Xiaflex injection procedures. The second Xiaflex injection procedure is performed 1 to 3 days after the first. The interval between treatment cycles is approximately six weeks. The treatment course consists of a maximum of 8 injection procedures.

References

1. Xiaflex® [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc; August 2022.
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 December 2, 2025.
3. Nehra A, Alterowitz R, Culkin D, et al. Peyronie's disease: AUA guideline. *J Urol*. 2015;194(3):745-753.