

Xiaflex® (collagenase clostridium histolyticum)

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

FDA-Approved Indications

Xiaflex is indicated for the treatment 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:

- At baseline (prior to initial injection of Xiaflex), had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees
- Will not be treated with more than a total of three injections (maximum) per affected cord
- 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:

- Had 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 a 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
- Is 18 years of age or older

Approval duration: 6 months

Dosing Guidelines

Dupuytren's contracture

The dose of Xiaflex is 0.58 mg per injection into a palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint.

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 intervals between treatment cycles is approximately six weeks. The treatment course consists of a maximum of 8 injection procedure.

References

1. Xiaflex® [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc; November 2019.
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 24, 2020.
3. Nehra A, Alterowitz R, Culkin D, et al. Peyronie's disease: AUA guideline. *J Urol*. 2015;194(3):745-753.