

SPECIALTY GUIDELINE MANAGEMENT

XIAFLEX (collagenase clostridium histolyticum)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Dupuytren's contracture: Chart notes or medical records indicating the affected joint, contracture, and a positive tabletop test (for new starts and continuation) and the number of injections the member has received (for continuation only).
- B. Peyronie's disease: Chart notes or medical records indicating palpable plaque, curvature, intact erectile function (for new starts and continuation) and the number of injections the member has received (for continuation only).

III. PRESCRIBER SPECIALTIES

- A. Dupuytren's contracture: The medication must be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture.
- B. Peyronie's disease: The medication must be administered by a healthcare provider experienced in the treatment of urological disease and who has completed the Xiaflex REMS program requirements.

IV. EXCLUSIONS

Coverage will not be provided for cosmetic use (e.g., cellulite reduction treatment).

V. CRITERIA FOR INITIAL APPROVAL

A. Dupuytren's contracture

Authorization of 6 months may be granted for the treatment of Dupuytren's contracture when all of the following criteria are met:

1. The member has a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint prior to initiating Xiaflex therapy.
2. The contracture is at least 20 degrees prior to initiating Xiaflex therapy.
3. The member had a positive tabletop test, defined as the inability to simultaneously place the affected finger(s) and palm flat against a table prior to initiating Xiaflex therapy.
4. The member is 18 years of age or older.
5. The member will receive up to 3 injections maximum per cord (4 weeks apart) as part of the current treatment.

B. Peyronie's disease

Authorization of 12 months may be granted for the treatment of Peyronie's disease when the following criteria are met:

1. The member has stable Peyronie's disease without clinical changes (e.g., worsening curvature) for at least three months.
2. The member has a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees prior to initiating Xiaflex therapy.
3. The member has intact erectile function (with or without medication).
4. The member is 18 years of age or older.
5. The member will receive a maximum of one treatment course with a maximum of 8 injections total, including any injections the patient has received for any previous treatment.

VI. CONTINUATION OF THERAPY

A. Dupuytren's contracture

Authorization of 6 months may be granted for the continuation of treatment for Dupuytren's contracture when all of the following criteria are met:

1. The member meets all initial authorization criteria.
2. The member is continuing with a treatment course for the same cord. For treatment of a new cord or a previously treated cord following recurrence, member must meet all initial authorization criteria.
3. The member has received less than 3 injections total per cord (4 weeks apart).

B. Peyronie's disease

Authorization of 12 months may be granted for the continuation of treatment for Peyronie's disease when all of the following criteria are met:

1. The member meets all initial authorization criteria.
2. The member has curvature deformity of at least 15 degrees at the time of the continuation request.
3. The member has received less than 8 injections total, including any injections the patient has received for any previous treatment.

VII. REFERENCES

1. Xiaflex [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2022.
2. Hurst LC, Badalamente MA, Hentz VR, et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. *N Engl J Med*. 2009;361(10):968-979.
3. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. *J Urol*. 2015;194(3):745-753.