

# Specialty Guideline Management

## Xiaflex

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name                         |
|------------|--------------------------------------|
| Xiaflex    | collagenase clostridium histolyticum |

### 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<sup>1</sup>

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

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

### Documentation

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

- 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).

- 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).

## Prescriber Specialties

- 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.
- 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.

## Exclusions

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

## Coverage Criteria

### Dupuytren’s contracture<sup>1,2</sup>

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

- 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.
- The contracture is at least 20 degrees prior to initiating Xiaflex therapy.
- 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.
- The member is 18 years of age or older.
- The member will receive up to 3 injections maximum per cord (4 weeks apart) as part of the current treatment.

### Peyronie’s disease<sup>1,3</sup>

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

- The member has stable Peyronie’s disease without clinical changes (e.g., worsening curvature) for at least three months.

- The member has a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees prior to initiating Xiaflex therapy.
- The member has intact erectile function (with or without medication).
- The member is 18 years of age or older.
- 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.

## Continuation of Therapy

### 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:

- The member meets all requirements in the coverage criteria section.
- 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 requirements in the coverage criteria section.
- The member has received less than 3 injections total per cord (4 weeks apart).

### 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:

- The member meets all requirements in the coverage criteria section.
- The member has curvature deformity of at least 15 degrees at the time of the continuation request.
- The member has received less than 8 injections total, including any injections the patient has received for any previous treatment.

## References

1. Xiaflex [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; July 2023.
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.