

# STANDARD MEDICARE PART B 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

1. Xiaflex is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.
2. 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### A. Dupuytren's contracture

Authorization of 6 months may be granted for the treatment of Dupuytren's contracture when 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.
2. The contracture is at least 20 degrees.
3. The member had a positive table top test, defined as the inability to simultaneously place the affected finger(s) and palm flat against a table.
4. The member will receive a maximum of 3 injections per cord (4 weeks apart).

##### 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. Xiaflex is prescribed for a member 18 years of age or older with stable Peyronie's disease.
2. The member has a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees with intact erectile function (with or without medication) at the start of therapy.
3. The member will receive a maximum of one treatment course or a maximum of 8 injections total, including any injections the member has received for any previous treatment.

<b>Reference number(s)</b>
2309-A

### III. CONTINUATION OF THERAPY

Authorization for 6 months (Dupuytren's contracture) or 12 months (Peyronie's disease) to complete a treatment course may be granted for all members (including new members) who are continuing with Xiaflex therapy when the following criteria are met:

- A. Xiaflex is requested for treating a diagnosis or condition enumerated in Section II.
- B. For Dupuytren's contracture, the member is continuing with a treatment course for the same cord and has received less than 3 injections total. Requests for treatment of a new cord or recurrence in a previously-treated cord must meet initial criteria for approval.
- C. For Peyronie's disease, the member has not yet completed treatment with the maximum of 8 injections, including any injections the member has received for any previous treatment and curvature deformity is 15 degrees or more.

### IV. REFERENCES

1. Xiaflex [package insert]. Endo Pharmaceuticals Inc.; November 2019.
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.