

ALASKA MEDICAID
Prior Authorization Criteria

Xiaflex®
(collagenase clostridium histolyticum)

FDA INDICATIONS AND USAGE¹

Xiaflex® is indicated for the treatment of adult patients with Dupuytren's Contracture (DC) with a palpable cord and for the treatment of adult men with Peyronie's Disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

APPROVAL CRITERIA^{1,2,3}

For Dupuytren's Contracture:

1. Patient is 18 years of age or older **AND;**
2. Patient has a confirmed diagnosis of Dupuytren's Contracture with a palpable cord **AND;**
3. Prescribe by or in consultation with a healthcare provider experienced in injection procedures of the hand and in the treatment of DC **AND;**
4. Patient has not received surgical treatment (e.g., fasciotomy) on the selected primary joint within the last 90 days **AND;**
5. If two injections (two vials) are requested, they are for one of the following (a or b):
 - a. One cord affecting two joints in the same finger **OR;**
 - b. Two cords affecting two joints in the same hand **AND;**
6. Documentation that the flexion deformity is causing functional limitations.

For Peyronie's Disease:

1. Patient is 18 years of age or older **AND;**
2. Patient has a confirmed diagnosis of Peyronie's Disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy **AND;**
3. Prescribed by or in consultation with a healthcare provider experienced in the treatment of male urological diseases **AND;**
4. Documentation that the patient has had stable disease defined by symptoms (I.E. penile curvature and pain) for at least 6 months **AND;**
5. Xiaflex is not being used for sexual or erectile dysfunction associated with Peyronie's Disease (7AAC 105.110) **AND;**
6. Must be used in conjunction with penile modeling.

DENIAL CRITERIA

1. Failure to meet approval criteria.

ALASKA MEDICAID
Prior Authorization Criteria

CAUTIONS¹

- Tendon rupture or serious injury to the injected finger/hand may occur.
- Corporal rupture (penile fracture) or other serious injury to the penis may occur.
- Xiaflex® is contraindicated for Peyronie's plaques that involve the penile urethra.
- Use caution in patients with abnormal anticoagulation.

DURATION OF APPROVAL

- Initial Approval: One treatment cycle
- Re-approval: One treatment cycle

(Administration no sooner than 4 week interval for Dupuytren's Contracture (up to 3 cycles in total) and no sooner than 6 week interval and has greater than 15 degree deformity for Peyronie's Disease (up to 4 cycles in total))

QUANTITY LIMITS

- 2 vials (injections) per treatment cycle

REFERENCES / FOOTNOTES:

1. Xiaflex® [Package Insert] Malvern, PA: US Endo Pharmaceuticals Inc.; June 2018. Available at: http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex_prescribing_information.html. Accessed on: October 23, 2019.
2. Schulze SM and Tursi JP. Post approval clinical experience in the treatment of Dupuytren's contracture with collagenase clostridium histolyticum (CCH): the first 1,000 days. *Hand*. 2014; 9: 447-458.
3. Randhawa, K, Shukla, C. Non-invasive treatment in the management of Peyronie's disease. *Therapeutic Advances in Urology*. 2019 Jan-Dec; 11. doi: 10.1177/1756287218823671. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6376494/#>. Accessed on: October 24, 2019.