SmartHealth

Ascension

Collagenase Clostridium Histolyticum

(Xiaflex®) J0775 (0.01 mg)

Covered with prior authorization

Requests for Xiaflex® (collagenase clostridium histolyticum) may be approved if the following criteria are met:

- Individual has a diagnosis of Dupuytren's contracture; **AND**
- Documentation is provided that product will be injected into a palpable palmar cord that impairs the individual's functional activities; **AND**
- Documentation is provided that the palpable cord measures either:
    - 20 degrees or more at the metacarpophalangeal joint; **OR**
    - 20 degrees or more at the proximal interphalangeal joint;
      AND
- The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals;

OR

- Individual has a diagnosis of Peyronie's disease; **AND**
- Disease is stable as defined by symptoms (such as, but not limited to penile curvature and pain) for at least 6 months (AUA); **AND**
- Documentation is provided that penile curvature is greater than or equal to 30 degrees and less than or equal to 90 degrees (AUA); **AND**
- Individual has intact erectile function with or without the use of medications (AUA); **AND**
- Documentation is provided that the individual has palpable penile plaque(s).

Requests for Xiaflex® (collagenase clostridium histolyticum) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- History of hypersensitivity to Xiaflex® (collagenase clostridium histolyticum) or to other collagenase products;
- Xiaflex® (collagenase clostridium histolyticum) may not be approved when the above criteria are not met and for all other indications;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;
- Individual is using for cosmetic indications, including, but not limited to, the treatment of cellulite; **OR**
- Individual is using for Peyronie's plaques that involve the penile urethra.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Xiaflex® (collagenase clostridium histolyticum) is a biologic that hydrolyzes native collagen. When injected into fibrous cords, Xiaflex® can lead to a reduction in contracture and improvement in range of motion of the affected joints. Xiaflex® is approved for the treatment of Dupuytren's contracture and Peyronie's disease. Dupuytren's disease is a progressive fibroproliferative disorder of an unknown origin affecting the hands causing permanent flexion contracture of the fingers. Surgery (fasciectomy) has been the mainstay treatment for Dupuytren's. An alternative to invasive surgery is injection of collagenase to break up the fibrous cord responsible for the contracture. Peyronie's disease is a connective tissue disorder which involves the growth of fibrous plaque in the soft tissue of the penis which can lead to symptoms such as penile curvature and pain. The 2015 American Urological Association (AUA) Peyronie's Disease guidelines recommend intralesional Xiaflex® in combination with modeling by the clinician and patient for the reduction of penile curvature in patients with stable Peyronie's disease, penile curvature >30° and <90°, and intact erectile function (with or without the use of medications).

Xiaflex® has a **black box warning** for corporal rupture (penile fracture) or other serious penile injury when administered for the treatment of Peyronie's disease. Due to the risks of corporal rupture and other serious penile injury, Xiaflex® is only available for the treatment of Peyronie's disease through a restricted REMS program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the Xiaflex® REMS website: http://www.xiaflexrems.com.

Key References Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Nehra A, Alterowitz R, Culkin DJ, et al: American Urological Association Education and Research, Inc., Peyronie's Disease: AUA Guideline. J Urol. 2015; 194(3):745-753.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.