Pharmacy Medical Necessity Guidelines:
Xiaflex® (collagenase clostridium histolyticum)

Effective: March 13, 2018

<table>
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<th>Prior Authorization Required</th>
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<th>Type of Review – Care Management</th>
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<td>Department to Review</td>
<td>PRECERT /MM</td>
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This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
* Tufts Health Plan Commercial Plans – large group plans
* Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
* Tufts Health Direct – Health Connector
* Tufts Health Together – A MassHealth Plan
* Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
* Tufts Health Freedom Plan – large group plans
* Tufts Health Freedom Plan – small group plans

Fax Numbers:
All plans except Tufts Health Public Plans:
Precert: 617.972.9409
Tufts Health Public Plans:
MM: 888.415.9055

Note: For Tufts Health Plan Medicare Preferred Members, refer to the Tufts Health Plan Medicare Preferred prior authorization criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS
Xiaflex (collagenase clostridium histolyticum) is indicated for the treatment of adult patients with Dupuytren’s contracture with a palpable cord.

Xiaflex (collagenase clostridium histolyticum) 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.

COVERAGE GUIDELINES

The plan may authorize coverage of Xiaflex (collagenase clostridium histolyticum) for Members when all of the following criteria are met:

Dupuytren’s contracture
1. Documented diagnosis of Dupuytren’s contracture with a palpable cord  
   AND
2. A positive “table top test” (defined as the inability to simultaneously place the affected finger and palm flat against a table top)  
   AND
3. Documented contracture of at least 40 degrees flexion for a metacarpophalangeal joint contracture or at least 20 degrees flexion for a proximal interphalangeal joint contracture  
   AND
4. Documentation that the flexion deformity results in functional limitations

Note: Injections should be administered at no less than 4 week intervals

Peyronie’s disease
1. Documented diagnosis of Peyronie’s disease with a palpable plaque  
   AND
2. Curvature deformity is at least 30 degrees at the start of therapy  
   AND
3. The prescriber is a urologist or otherwise experienced in the treatment of male urological diseases  
   AND
4. Peyronie’s disease symptoms have been present for at least 12 months  
   AND
5. Member is 18 years of age or older

Note: Injections should be administered at no less than six-week intervals.
LIMITATIONS

1. For the diagnosis of Dupuytren’s contracture:
   a. Authorization will be limited to metacarpophalangeal joint contractures or proximal interphalangeal joint contractures.
   b. Authorization will be limited per joint as follows: one injection per month for a maximum of three injections per cord.

2. For the diagnosis of Peyronie’s disease:
   a. Initial authorization will be limited to one treatment cycle consisting of two Xiaflex injection procedures and one penile modeling procedure.
   b. Subsequent authorization(s) for additional treatment cycles may be given if the curvature deformity is more than 15 degrees after the first, second or third treatment cycle, or if the prescribing healthcare provider determines that further treatment is clinically indicated.
   c. For each plaque causing the curvature deformity, up to four treatment cycles may be approved (maximum of eight injection procedures and four modeling procedures).

CODES

The following HCPCS/CPT code(s) are:

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<th>Code</th>
<th>Description</th>
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<td>J0775</td>
<td>Injection, collagenase, clostridium histolyticum, 0.01 mg</td>
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REFERENCES

APPROVAL HISTORY

September 14, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- September 13, 2011: No changes
- September 11, 2012: No changes
- September 10, 2013: No changes
- January 13, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- February 9, 2016: No changes
- April 12, 2016: Effective 10/01/2016, Medical Necessity Guideline applies to Tufts Health Together.
- March 13, 2018: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.