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

Effective: February 12, 2019

<table>
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<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Not Covered</th>
<th>Type of Review – Clinical Review</th>
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Pharmacy (RX) or Medical (MED) Benefit

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<tr>
<th>Pharmacy (RX) or Medical (MED) Benefit</th>
<th>Department to Review</th>
<th>Fax Numbers:</th>
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<td>MED/RX</td>
<td>Department to Review</td>
<td>All plans except Tufts Health Public Plans: Precert: 617.972.9409</td>
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<td>Tufts Health Public Plans: MM: 888.415.9055</td>
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These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

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

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**
Xiaflex (collagenase clostridium histolyticum) is a combination of bacterial collagenases indicated for the treatment of:
- **Dupuytren’s contracture**
  - Adult patients with Dupuytren’s contracture with a palpable cord
- **Peyronie’s disease**
  - 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 four 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 prescribing physician is a urologist or otherwise experienced in the treatment of male urological diseases
   AND
4. Documentation that Peyronie’s disease symptoms have been present for at least 12 months
   AND
5. The Member is at least 18 years of age
Note: Injections should be administered at no less than six week intervals.

LIMITATIONS

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

- For the diagnosis of Peyronie’s disease:
  - Initial authorization will be limited to one treatment cycle consisting of two Xiaflex injection procedures and one penile modeling procedure.
  - 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.
  - 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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<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:
2. September 13, 2011: No changes.
4. September 10, 2013: No changes.
7. January 1, 2016: Administrative change to rebranded template.
8. February 9, 2016: No changes
12. February 12, 2019: 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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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.