Xiaflex® (collagenase clostridium histolyticum)

**Last Review Date:** July 25th, 2018

**Number:** MG.MM.ME.cC5

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**Definitions**

Xiaflex® (collagenase clostridium histolyticum) is a biologic injectable that enzymatically breaks down collagen when injected directly into a Dupuytren's cord. This can result in contracture reduction and range of motion improvement.

**Dosing**

Max units (per dose and over time):

- Dupuytren’s contracture:
  - 58 billable units per cord up to 3 times approximately 4 weeks apart
- Peyronie’s Disease:
  - 58 billable units on each of 2 days 1-3 days apart every 6 weeks a maximum of 4 times

**Guideline**

Xiaflex (collagenase clostridium histolyticum) is considered medically necessary for the following diagnosis when the subsequent criteria are met:

**Dupuytren’s Contracture:**

- Patient is 18 years of age or older; **AND**
- Patient has a palpable cord; **AND**
- Patient’s with recent onset disease with signs of inflammation (tenderness, nodules, or tenosynovitis) have had an ineffective trial with a corticosteroid injection; **AND**
- Patient presents with one of the following:
  - Considerable function impairment as demonstrated by documentation of flexion deformities >20 degrees at the MP or PIP joint; **OR**
  - Presence of flexion deformities (described above) and inflammation that has been refractory to steroid and hand therapy
Peyronie’s Disease:
- Patient is 18 years of age or older; **AND**
- Patient has palpable plaque; **AND**
- Patient has a curvature deformity of at least 30 degrees at the start of therapy

Coverage for Xiaflex may be renewed for the following diagnosis when subsequent criteria are met:

- Patient’s curvature deformity is 15 degrees or greater

**Limitations/Exclusions**

- Approval will be granted for 12 weeks for a diagnosis of Dupuytren’s Contracture per cord and may not be renewed
- Subsequent approvals for a diagnosis of Dupuytren’s Contracture will require a new authorization
- Approval will be granted for 6 weeks for a diagnosis of Peyronie’s Disease and may be renewed a maximum of 3 times
- As serious complications or damage may occur, Xiaflex should only be administered by a health care professional experienced with hand injections (for Dupuytren’s contracture) or urologists (for Peyronie’s disease) who have received certification in the [XIAFLEX Risk Evaluation and Mitigation Strategy (REMS) Program](#).

**Applicable Procedure Codes**

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<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>20550</td>
<td>Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar “fascia”)</td>
</tr>
<tr>
<td>20527</td>
<td>Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren’s contracture)</td>
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<tr>
<td>26341</td>
<td>Manipulation, palmar fascial cord (ie, Dupuytren’s cord), post-enzyme injection (eg, collagenase), single cord</td>
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<tr>
<td>29130</td>
<td>Application of finger splint; static</td>
</tr>
<tr>
<td>54200</td>
<td>Injection procedure for Peyronie disease;</td>
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<tr>
<td>54235</td>
<td>Injection of corpora cavernosa with pharmacologic agent(s) (eg, papaverine, phentolamine)</td>
</tr>
<tr>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
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<tr>
<td>J0775</td>
<td>Injection, collagenase, clostridium histolyticum, 0.01 mg</td>
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**Applicable Diagnosis Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>M72.0</td>
<td>Palmar fascial fibromatosis [Dupuytren]</td>
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<tr>
<td>N48.6</td>
<td>Induration penis plastica</td>
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References

