Xiaflex® (collagenase clostridium histolyticum)

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Medical Guideline Disclaimer

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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:

Peyronie’s Disease:
- 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

<table>
<thead>
<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 (e.g., plantar “fascia”)</td>
</tr>
<tr>
<td>20527</td>
<td>Injection, enzyme (e.g., collagenase), palmar fascial cord (i.e., Dupuytren’s contracture)</td>
</tr>
<tr>
<td>26341</td>
<td>Manipulation, palmar fascial cord (i.e., Dupuytren’s cord), post-enzyme injection (e.g., collagenase), single cord</td>
</tr>
<tr>
<td>29130</td>
<td>Application of finger splint; static</td>
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<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) (e.g., papaverine, phentolamine)</td>
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<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

