I. Length of Authorization

- Dupuytren’s contracture: Coverage will be for 3 months and is eligible for renewal for a maximum of 3 injections per joint.
- Peyronie’s Disease: Coverage will be for 1 month and is eligible for renewal for a maximum of 4 treatment cycles for each plaque causing the curvature deformity.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Xiaflex 0.9mg injection: 2 vials per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:
   - Dupuytren’s contracture: 180 billing units every 28 days
   - Peyronie’s Disease: 180 billing units every 42 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old: **AND**

**Dupuytren’s contracture †**

- Patient has a palpable cord: **AND**
- Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint: **AND**
- Documentation of a positive “table top test” defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top: **AND**
- Documentation that the flexion deformity results in functional limitations

**Peyronie’s Disease†**

- Patient has a palpable plaque on penis: **AND**
- Patient has penis curvature deformity of at least 30 degrees: **AND**
• Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
• The patient has not received a Xiaflex injection for this condition within the past 6 weeks
† FDA-labeled indication(s)

**IV. Renewal Criteria**

Coverage can be renewed based upon the following criteria:

• Patient continues to meet the criteria identified in section III: **AND**
• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions; excessive injection site hemorrhage; tendon ruptures or other serious injury to the injected extremity; corporal rupture (penile fracture) or other serious injury to the penis; **AND**

**Dupuytren’s contracture only**

• Disease response as indicated by reduction in contracture of the selected primary joint compared to baseline; **AND**
• Patient has not exceeded 3 injections per joint.

**Peyronie’s Disease only**

• Disease response as indicated by improvement in penile curvature deformity; **AND**
• Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
• The patient has not received a Xiaflex injection for this condition within the past 6 weeks; **AND**
• Patient has penis curvature deformity of at least 15 degrees after the first, second, or third treatment cycle

**V. Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dupuytren’s contracture</td>
<td>Up to 0.58mg per injection every 4 weeks for a total of 3 doses per cord. Up to two joints in the same hand may be treated during a treatment visit.</td>
</tr>
<tr>
<td>Peyronie’s Disease</td>
<td>Inject 0.58mg into the target plaque once on each of two days, 1 to 3 days apart, according to the injection procedure. For each plaque causing the curvature deformity, up to four treatment cycles may be administered. Each treatment cycle may be repeated at approximately 6 week intervals.</td>
</tr>
</tbody>
</table>

**VI. Billing Code/Availability Information**

**J-code:**
This HNE clinical criteria is only a screening tool. It is not for final clinical or payment decisions. All care decisions are solely the responsibility of your healthcare provider. This HNE clinical criteria is confidential and proprietary. It applies only to this review.

J0775 – Injection, collagenase, clostridium histolyticum, 0.01 mg: 0.01mg = 1 billable unit

NDC:
Xiaflex 0.9mg powder for injection: 66887-0003-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M72.0</td>
<td>Palmar fascial fibromatosis [Dupuytren]</td>
</tr>
<tr>
<td>N48.6</td>
<td>Induration penis plastica</td>
</tr>
</tbody>
</table>

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
</tbody>
</table>
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