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/cord.
- Peyronie’s Disease: Coverage will be for 1 month and is eligible for renewal for a maximum of 4 total 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 stable disease with penis curvature deformity of > 30 and < 90 degrees: **AND**
  - Patient has intact erectile function (with or without use of medications): **AND**
• Patient does not have isolated hourglass deformity or calcified plaque; **AND**
• The plaque(s) do not involve the penile urethra; **AND**
• Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
• The patient has not received a collagenase 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**

**Dupuytren’s contracture**

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions; abnormal coagulation; tendon ruptures or other serious injury to the injected extremity, etc.; **AND**
• 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/cord.

**Peyronie’s Disease**

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions; abnormal coagulation; corporal rupture (penile fracture) or other serious injury to the penis, etc.; **AND**
• Disease response as indicated by improvement in penile curvature deformity; **AND**
• Further treatment is clinically indicated as the patient has penis curvature deformity of at least 15 degrees after the previous treatment cycle(s); **AND**
• Patient has not exceeded 4 total treatment cycles for each plaque causing the curvature deformity; **AND**
• The patient has not received a collagenase injection for this condition within the past 6 weeks

**V. Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dupuytren’s contracture</td>
<td>Inject 0.58 mg into each palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Peyronie’s Disease</th>
<th>Each treatment cycle entails injection of 0.58 mg into the target plaque once on each of two days, 1 to 3 days apart, according to the injection procedure.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• For each plaque causing the curvature deformity, up to four total treatment cycles may be administered. Each treatment cycle may be repeated at approximately 6 week intervals.</td>
</tr>
<tr>
<td></td>
<td>• If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles should not be administered</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

**HCPCS-Code:**

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

**NDC:**

Xiaflex 0.9 mg 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>
</tbody>
</table>
This 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.

N48.6 Induration penis plastica

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>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto Government Benefit Administrators, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
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<td>National Government Services, Inc. (NGS)</td>
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<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
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