Xiaflex® (collagenase clostridium histolyticum)

FDA Approval Date: 02/03/2010
HCPCS: J0775
Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the below criteria are met:
   a. Diagnosis of Dupuytren’s contracture
      i. A finger flexion contracture with a palpable cord of at least one finger (other than the thumb) involving the metacarpophalangeal (MP) joint or the proximal interphalangeal (PIP) joint
      ii. Administering physician must be a surgeon who has experience and training in hand surgeries
   b. Diagnosis of Peyronie’s disease
      i. Diagnosis made in consultation with a urologist
      ii. Palpable plaque and curvature deformity of 30° or greater at start of therapy
      iii. Treatment with at least ONE of the following was ineffective, contraindicated, or not tolerated: intralesional verapamil, pentoxifylline, or verapamil gel
   c. 18 years of age or older
   d. Facility must be enrolled to receive Xiaflex through Xiaflex REMS™

B. Quantity Limitations, Authorization Period, and Renewal Criteria
   a. Quantity Limit for Dupuytren’s contracture
      i. One dose per cord per 28 days
      ii. Initial Authorization Period: 3 months
      iii. Maximum of 3 doses per cord
   b. Quantity Limit for Peyronie’s disease
      i. Two injections per plaque per 28 days
      ii. Initial Authorization Period: 3 months
      iii. Maximum 4 treatment cycles (2 injections/cycle) per plaque

C. Xiaflex is considered investigational when used for all other conditions, including but not limited to:
   a. Adhesive capsulitis (frozen shoulder)
   b. herniated intervertebral discs
   c. hypertrophic scars
   d. scarred tendons

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.
Therapeutic Considerations:

A. FDA Approved Indication(s)
   a. For the treatment of adult patients with Dupuytren’s contracture with a palpable cord
   b. For adult men with Peyronie’s disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees

   *Please refer to most recent prescribing information.

B. Background Information
   i. Dupuytren’s syndrome is a thickening of the fascia that can develop into a cord and cause a finger to contract towards the palm. Treatment has included surgery that would remove the abnormal tissue. Collagenase clostridium histolyticum (CCH) is a proteinase that hydrolyzes collagen which may result in lysis of collagen deposits
   ii. Treatment for severe cases has been surgical. No other known treatment is currently available
   iii. Peyronie’s disease is a disorder that results in varying degrees of penile curvature deformity, disease bother, sexual dysfunction, emotional distress, loss of self-esteem, and depression. PD is the development of collagen plaque on the shaft of the penis that may harden and reduce flexibility, thus causing pain and deforming and bending of the penis during an erection
   iv. Peyronie’s disease is a localized connective tissue disorder characterized by changes in the collagen composition in the tunica albuginea. These changes cause an abnormal scar formation known as Peyronie’s plaque, which is typically a palpable bump under the skin. Microvascular trauma resulting from excessive bending or injury to the penis (possibly during sexual activity) is thought to be an important trigger for the inflammatory response and plaque development characteristic of Peyronie’s disease
   v. Estimated prevalence of approximately 5%, however is thought to be underdiagnosed and undertreated. Approximately 65,000-120,000 new PD diagnoses annually, but only 5,000-6,500 are treated
   vi. Intralesional verapamil has shown higher efficacy rates in comparison with other alternatives (examples: pentoxifylline and verapamil gel) as the injection acts directly at the site of injury

C. Efficacy

   *Please refer to most recent prescribing information.

D. Medication Safety Considerations

   Black Box Warning: No

   *Please refer to most recent prescribing information.
E. Dosing and Administration

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Dosing Range</th>
<th>How Supplied</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dupuytren’s Contracture</td>
<td>0.58 mg per cord at 4 week intervals for a maximum of 3 doses. The 0.58 mg dose can be divided into 3 injections per cord in one day</td>
<td>Single use 0.9 mg vial</td>
<td>Maximum of 3 doses at 28-day intervals</td>
</tr>
<tr>
<td>Peyronie’s Disease</td>
<td>0.58 mg per injection administered into a Peyronie’s plaque, up to four treatment cycles (2 injections/cycle)</td>
<td>Single use 0.9 mg vial</td>
<td>Maximum of 4 cycles at 28-day intervals</td>
</tr>
</tbody>
</table>

*Please refer to most recent prescribing information.

References

1. BCBSM Medical Policy; BCR # 110NAFX07 for Collagenase Clostridium Histolyticum (Xiaflex®) for Injection effective date:11/01/2011
2. SPPC review: 2010 Specialty Pharmacy Combined Capacity (SPPC) report # 10.12.02
3. Xiaflex® [package insert], Malvern, PA 19355 USA: Auxilium Pharmaceuticals, Inc.; Revised 10/2010
4. ©2011 Regence RX-Therapeutic Class Review™- Bone and Joint Collagenase clostridial histolyticum, CCH (Xiaflex®)[ Auxilium Pharmaceuticals]
7. American Urological Association Diagnosis and Treatment of Peyronie’s Disease. [Cited 01/04/2016]; Available at: https://www.auanet.org/common/pdf/education/clinical-guidance/Peyronies-Disease-Algorithm.pdf
<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
</table>
| 1.0| Effective Date: 2/9/2012 | - Custom/Clinical Formulary: N/A  
- Custom formulary chapter: N/A  
- Part D: Specialty  
- Part D formulary chapter: Diagnostics and Other Miscellaneous  
- Recommended criteria and QL |
| 1.1| Effective Date: 5/8/2014 | Criteria update                                                                   |
| 1.2| Effective Date: 5/5/2016 | Criteria update with changes to current step therapy                              |
| 1.3| Effective Date: 5/4/2017 | Annual Review                                                                     |
| 1.4| Effective Date: 11/9/2017 | Updated Step Therapy                                                              |

*The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm)*