Overview
Xiaflex is a combination of bacterial collagenases indicated for:
1. The treatment of adult patients with Dupuytren’s contracture with a palpable cord
2. The treatment of adult men with Peyronie’s disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

Coverage Guidelines
Authorization may be granted for members who are currently receiving and are stable on Xiaflex for an FDA approved indication excluding when the product is obtained as samples or via manufacturer’s patient assistance program.

OR
Approval will be granted if the member meets the following diagnosis specific criteria:

Dupuytren’s Contracture
1. Member has a diagnosis of Dupuytren’s contracture with a palpable cord

Peyronie’s Disease
1. Member has a documented diagnosis of Peyronie’s disease with a palpable plaque AND
2. Member is 18 years of age or older AND
3. Peyronie’s disease symptoms have been present for at least 12 months AND
4. Curvature deformity is at least 30 degrees at the start of therapy AND
5. Member has had an inadequate response, contraindication or intolerance to a trial (6 months or greater) of appropriate alternative treatments such as pentoxifylline or intralesional verapamil AND
6. Prescriber is a urologist or otherwise experienced in the treatment of male urological diseases
Continuation of Therapy
Reauthorization for Peyronie’s disease may be granted if the curvature deformity is greater than 15 degrees after the first, second or third treatment cycle.

Maximum of four treatment cycles or a total of eight injection procedures and 4 penile modeling procedures.

Limitations
The following quantity limits apply:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Initial Approval</th>
<th>Reauthorization</th>
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</thead>
<tbody>
<tr>
<td>Dupuytren’s Contracture</td>
<td>Up to 3 injections per cord, 2 cords per hand</td>
<td>Maximum of four treatment cycles or a total of eight injection procedures and 4 penile modeling procedures.</td>
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<tr>
<td>Peyronie’s Disease</td>
<td>Approvals will be granted for 6 months</td>
<td>Maximum of four treatment cycles or a total of eight injection procedures and 4 penile modeling procedures.</td>
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References
2. Up-To-Date; Peyronie’s Disease: Diagnosis and Medical Management Authors: William O Brant, MD, FACS, FECSM, Anthony J Bella, MD, FRCSC, Updated: May 26, 2016.

Review History
11/28/2016 – Reviewed
11/27/2017 – Reviewed
03/18/2020 – Reviewed and Updated P&T Mtg
7/22/2020 – reviewed and Updated July P&T Mtg; updated Approval Limitation to include duration of approval. Effective 10/01/20

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