

**Xiaflex® (collagenase clostridium histolyticum)**  
**Effective 10/01/2020**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### 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:

Dupuytren’s Contracture	Approvals will be granted for 3 months  Up to 3 injections per cord, 2 cords per hand
Peyronie’s Disease	Approvals will be granted for 6 months  <u>Initial Approval</u> Up to one treatment cycle of two Xiaflex injection procedures and one penile modeling procedure.  <u>Reauthorization</u> Maximum of four treatment cycles or a total of eight injection procedures and 4 penile modeling procedures.

**References**

1. Package Insert, **XIAFLEX- collagenase clostridium histolyticum**, Auxilium Pharmaceuticals, LLC Malvern, PA 19355, 8/2016.
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.

