

Policy Title:	Xiaflex (Clostridium histolyticum) (Intralesional)		
Policy Number:	000635	Department:	PHA
Effective Date:	12/12/2018		
Review Date:	12/12/2018		
Revision Date:	12/12/2019		

Purpose: To support safe, effective and appropriate use of Xiaflex (Clostridium histolyticum).

Scope: Medicaid, Exchange, Integrity

Policy Statement:

Xiaflex (Clostridium histolyticum) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Xiaflex (Clostridium histolyticum) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria Coverage for Dupuytren’s contracture:

- Patient is at least 18 years of age
- Patient has a documented diagnosis of Dupuytren’s contracture and a palpable cord;
- Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint;
- 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;
- Documentation that the flexion deformity results in functional limitations

Initial Criteria Coverage for Peyronie’s Disease:

- Patient is at least 18 years of age
- Documented diagnosis of Peyronie’s disease with a palpable plaque
- Patient has penis curvature deformity of at least 30 degrees;
- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity;

- The patient has not received a Xiaflex injection for this condition within the past 6 weeks

Continuation of therapy:

- Patient is tolerating treatment
- For Dupuytren's contracture:
 - Disease response as indicated by reduction in contracture of the selected primary joint compared to baseline;
 - Patient has not exceeded 3 injections per joint.
- For Peyronie's Disease:
 - Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity;
 - The patient has not received a Xiaflex injection for this condition within the past 6 weeks;
 - Patient has penis curvature deformity of at least 15 degrees after the first, second, or third treatment cycle

Coverage durations:

- Dupuytren's contracture: 3 months and can be renewed up to a maximum of 3 injections per cord (maximum 116 units every 28 days)
- Peyronie's Disease: 1 month and can be renewed up to a maximum of 4 treatment cycles (maximum 116 units every 28 days)

Investigational use: Xiaflex (*Clostridium histolyticum*) is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Additional information:

Indications:

- For the treatment of adult patients with Dupuytren's contracture with a palpable cord and Xiaflex is indicated for 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

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
11900	Inject skin lesions, up to and including 7 lesions
J0775	Injection, collagenase, clostridium histolyticum, 0.01mg

References:

Xiaflex (collagenase clostridium histolyticum) package insert. Malvern, PA: Auxilium Pharmaceuticals, Inc.; June 2018.