

DRUG DETERMINATION POLICY

Title: DDP-37 Xiaflex

Effective Date: 06/29/2021



Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Xiaflex is a specialty drug indicated for specific diagnoses and is associated with significant adverse effects. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and to lessen severity of adverse effects..

3.0 Clinical Determination Guidelines:

Document the following with chart notes

A. Dupuytren's Contracture.

1. Diagnosis and severity [must meet both listed below]:
 - a. Presence of a palpable cord.
 - b. Functional impairment: metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joint contracture of at least 20 degrees.
2. Dosage regimen:
 - a. Initial: 0.58mg per injection into a palpable cord (only 0.9mg vial).
 - b. Repeat (if needed): every four weeks to a maximum of three times per cord.

B. Peyronie's Disease.

1. Diagnosis and severity [must meet all listed below]:

- a. Presence of a palpable plaque.
- b. Curvature deformity: at least 30 degrees, but less than 90 degrees at the start of therapy.
- c. Symptoms: pain and/or sexual dysfunction.

2. Dosage regimen:

- a. Initial treatment cycle: 0.58mg per injection, repeat one to three days later (only 0.9mg vial).
- b. Repeat:
 - Curvature deformity: must be more than 15 degrees after initial treatment cycle.
 - Total of up to four treatment cycles (total of eight injections per course).
 - One treatment course limit: the safety of more than one treatment course is not known.

4.0 Coding:

AFFECTED CODES				
HCPCS	Brand Name	Generic Name	Billing Units (1U)	Prior Approval
J0775	Xiaflex	Collagenase clostridium histolyticum	0.01mg	Yes

5.0 References, Citations & Resources:

1. Xiaflex® (collagenase clostridium histolyticum) Package Insert. Auxilium Pharmaceuticals, Inc. 2014 Oct.
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Xiaflex, accessed May 2021.
3. Clinical efficacy, safety and tolerability of collagenase Clostridium histolyticum for the treatment of Peyronie Disease in 2 large double-blind, randomized, placebo controlled phase 3 studies. *Journal of Urology*. 2013; 190(1):199-207.
4. Injectable collagenase Clostridium histolyticum for Dupuytren’s Contracture. *NEJM*. 2009; 361:968-79.

6.0 Appendices:

See page 3.

7.0 Revision History:

Original Effective Date: 06/24/2015

Next Review Date: 05/26/2022

Revision Date	Reason for Revision
8/19	Moved to new format, replaced abbreviations
4/20	Annual review; criteria instructional language, replaced abbreviations, approved at June P&PT Committee meeting.
5/21	Annual review, clarified criteria instructions, replaced abbreviations, vial size

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	Requirements
Xiaflex® for Peyronie's collagenase	<ul style="list-style-type: none"> • Genitourinary: penile - hematoma (66%), swelling (55%), pain (45%), popping sensation (13%) • Dermatology: hemorrhagic blister (5%) 	<ul style="list-style-type: none"> • Hypersensitivity to prescriptions • Concomitant anticoagulants &/or antiplatelet drug: injection site bruising 	<ul style="list-style-type: none"> • Purpose: warn regarding risk of corporal rupture/other serious injury • Site: http://www.xiaflex.com/hcp
Xiaflex® for Dupuytren's collagenase	<ul style="list-style-type: none"> • Cardiovascular: peripheral edema (73-77%) • Dermatology: hemorrhagic blister (12%), itching (4-15%), bruising (59-70%) • Musculoskeletal: limb pain (35-51%) • Pregnancy: adverse events have not been in animal reproductive studies 	<ul style="list-style-type: none"> • Hypersensitivity reactions • Concomitant anticoagulants &/or antiplatelet drug: injection site bruising 	<ul style="list-style-type: none"> • Medication guideline • Site: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM200615