	<b>Johns Hopkins HealthCare LLC</b> <b>Pharmacy Public</b> <b>Medical Management Drug Policies</b>	<i>Policy Number</i>	MMDP063
		<i>Effective Date</i>	06/01/2022
		<i>Review Date</i>	04/20/2022
	<i>Subject</i> <b>Xiaflex</b>	<i>Revision Date</i>	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

**Keywords:** Xiaflex

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## **I. POLICY**


- A. Xiaflex (collagenase clostridium histolyticum) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

## **II. POLICY CRITERIA**

- A. Xiaflex may be approved for patients who meet the following:
1. Dupuytren's contracture
    - a. Documentation has been submitted showing the following:
      - I. Patient has a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint
      - II. The contracture is at least 20 degrees
      - III. Patient has had a positive table top test, defined as the inability to simultaneously place the affected finger and palm flat against a table
      - IV. Patient will receive a maximum of 3 injections per cord (4 weeks apart) as part of the requested treatment
  2. Peyronie's disease
    - a. Documentation has been submitted showing the following:
      - I. Patient is 18 years of age or older
      - II. Patient has stable Peyronie's disease without clinical changes (e.g., worsening curvature) for at least 3 months
      - III. Patient has a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees
      - IV. Patient has intact erectile function (with or without medication)
      - V. Patient will receive a maximum of one treatment course with a maximum of 8 injections total, including any injections the patient has received for any previous treatment.

## **III. AUTHORIZATION PERIOD/LIMITATIONS**

- A. Dupuytren's contracture:
1. Initial approval will be limited to 6 months of therapy
  2. Continuation of therapy may be approved in 6-month intervals with documentation showing the following:

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- a. Patient still meets the initial coverage criteria
- b. Patient is continuing with a treatment course for the same cord.
- c. Patient has received less than 3 injections total per cord, 4weeks apart.
  - I. (\*For treatment of a new cord or a previously-treated cord that has recurrence, the patient must meet the initial coverage criteria)
3. The member has received less than 3 injections total per cord (4 weeks apart).
- B. Peyronie's disease
  1. Initial approval will be limited to 12 months of therapy
  2. Continuation of therapy may be approved in 12-month intervals with documentation showing the following:
    - a. Patient still meets the initial coverage criteria
    - b. Patient has curvature deformity of at least 15 degrees after previous treatment
    - c. Patient has received less than 8 injections total, including any injections the patient has received for any previous treatment.

#### **IV. EXCLUSIONS**

- A. Xiaflex will not be covered for the following:
  1. Any indications or uses that are not FDA-approved, or guideline-supported

#### **V. RECOMMENDED DOSAGE**

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

#### **VI. CODES**


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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, collagenase, Clostridium bostolyticum, 0.01 mg	J0775

#### **VII. REFERENCES**

1. Xiaflex [prescribing information]. Endo Pharmaceuticals Inc.; December 2021.
2. Hurst LC, Badalamente MA, Hentz VR, et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med. 2009;361(10):968-979.
3. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. J Urol. 2015;194(3):745-753.

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## VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Dates: 04/20/2022

Revision Dates: