

Pharmacy Benefit Determination Policy

Policy Subject: Xiaflex	Dates:
Policy Number: SHS PBD47	Effective Date: June 24, 2015
Category: Surgical Enzyme	Revision Date:
Policy Type: <input checked="" type="checkbox"/> Medical <input type="checkbox"/> Pharmacy	Approval Date: July 6, 2017
Department: Pharmacy	Next Review Date: June 2018
Product (check all that apply):	Clinical Approval By:
<input checked="" type="checkbox"/> Group HMO/POS	Medical Directors
<input checked="" type="checkbox"/> Individual HMO/POS	PHP: Peter Graham, MD; SPHN: Harman Nagler, MD
<input checked="" type="checkbox"/> PPO	Pharmacy and Therapeutics Committee
<input checked="" type="checkbox"/> ASO	PHP: Peter Graham, MD; Sparrow ASO: Harman Nagler, MD

Policy Statement:
Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Xiaflex through the Medical Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:
J-code: J0775

Clinical Determination Guidelines:
<p>Document the following with chart notes</p> <p>A. Dupuytren's Contracture</p> <ol style="list-style-type: none"> 1. Disease severity: The following criteria must be met: <ol style="list-style-type: none"> a. Presence of a palpable cord b. Functional impairment: MCP or PIP joint contracture of ≥ 20 degrees 2. Dosing: <ol style="list-style-type: none"> a. Initial: 0.58 mg/injection into a palpable cord. b. Repeat (if needed): every 4 wks. to a max. of 3x's/cord. <p>B. Peyronie's Disease</p> <ol style="list-style-type: none"> 1. Disease severity: All of the following criteria must be met: <ol style="list-style-type: none"> a. Presence of a palpable plaque b. Curvature deformity: ≥ 30 degrees, but $<$ or $=$ to 90 degrees at the start of therapy c. Symptoms: Pain &or sexual dysfunction 2. Dosing: 1 treatment course limit <ol style="list-style-type: none"> a. Initial Tx Cycle: 0.58 mg/injection x 2 (1-3 days apart) b. Repeat: Up to 4 tx cycles (8 inject./tx course) <p>Appendix I: Patient Safety and Monitoring</p>




Pharmacy Benefit Determination Policy

Drug	Adverse Reactions	Monitoring	REMS
Xiaflex® for Peyronie's	<ul style="list-style-type: none"> • GU: Penile - hematoma (66%), swelling (55%), pain (45%), popping sensation (13%) • Derm: Hemorrhagic blister (5%) 	<ul style="list-style-type: none"> • Hypersensitivity rxs • Concomitant anticoagulants &/or antiplatelet drug: Injection site bruising 	<ul style="list-style-type: none"> • Purpose: Warn re risk of corporal rupture/other serious injury • Prescriber/healthcare site: Certification, med guide dispensed w product • Web: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM200615
Xiaflex® for Dupuytren's	<ul style="list-style-type: none"> • CV: Peripheral edema (73-77%) • Derm: Hem. blister (12%), itching (4-15%), bruising (59-70%) • MSK: limb pain (35-51%) 	<ul style="list-style-type: none"> • Hypersensitivity reactions • Concomitant anticoagulants &/or antiplt drug: Injection site bruising 	Not Needed for Dupuytren's contracture

References and 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 2017.
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.

Approved By:

	7/6/17
Peter Graham, MD – PHP Executive Medical Director	Date
	7/6/17
Harman Nagler, MD – SPHN Executive Medical Director	Date
	7/6/17
Human Resources	Date