Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH031.1024	**MISCELLANEOUS PRODUCTS** **XIAFLEX®** (collagenase clostridium histolyticum kit)
Effective Date: 1/1/2025	**Review/Revised Date**: 03/20, 07/20, 11/20, 08/21, 09/22, 09/23, 08/24 (KN)
Original Effective Date: 07/20	**P&T Committee Meeting Date**: 04/20, 08/20, 12/20, 10/21, 10/22, 10/23, 10/24
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicare Part B
Medicaid

POLICY CRITERIA:

COVERED USES:
Dupuytren's contracture and Peyronie's disease, subject to criteria below

For Medicaid: Peyronie's disease is considered "below the line". Therefore, coverage is dependent on whether the condition adversely affects, or is secondary to, a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

REQUIRED MEDICAL INFORMATION:
Initial Authorization Criteria:
For **Dupuytren's contracture (DC)**:
1. Finger flexion contracture of at least 20° with a palpable cord in a metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint
2. Documentation that affected joint has not had surgical intervention within the previous 90 days

For **Peyronie's disease (PD):**
1. Patient's disease is stable, defined as unchanged degree of curvature for at least three months
2. Patient has a curvature of the penis that is between 30 and 90 degrees with a palpable cord, or a cord that is documented through ultrasound
3. Patient has intact erectile function, with or without the use of medications

Reauthorization Criteria:
For **DC**:
1. Documentation of fewer than three total injections in affected cord.

For **PD**
1. Documentation that the curvature of the penis remains greater than 15 degrees. Limited to eight total injections per lifetime.

EXCLUSION CRITERIA:
- PD involving the urethra.
- More than three total injections per affected cord for DC
- More than eight total injections per lifetime for PD.

AGE RESTRICTIONS:
Approved for 18 years and older

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
For **DC**:
Initial authorization will be approved for three months for a maximum of three treatment courses. Reauthorization will be approved for three months, not to exceed three injections per affected cord.

For **PD**:
Initial authorization will be approved for three months, not to exceed four injections. Reauthorization will be approved for six months, not to exceed eight injections per lifetime.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Xiaflex® contains purified collagenase clostridium histolyticum, consisting of two microbial collagenases in a defined mass ratio. Collagenases are proteinases that hydrolyze collagen in its native triple helical conformation under physiological conditions, resulting in lysis of collagen deposits. Dupuytren's contracture (DC) cords are typically comprised of collagen and Peyronie's disease (PD) is caused by the buildup of collagen plaques in the penis that causes a curvature.

FDA APPROVED INDICATIONS:
- Treatment of adult patients with DC (ICD-10 M72.0) with a palpable cord
- Treatment of adult men with PD (ICD-10 N48.6) with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

POSITION STATEMENT:
DC is a condition that affects the fascia in the palm and fingers. It is characterized by fascial thickening that can progress to longitudinal bands, referred to as cords, that can limit mobility and function of the hand and fingers. It causes flexion of the metacarpophalangeal (MCP) joint, proximal interphalangeal (PIP) joint, or both. Treatment can involve steroid injections, surgery (most common for advanced disease), or injection of collagenase clostridium histolyticum.

PD is characterized by a buildup of collagen plaques that can cause a curvature deformity of the penis. This can be associated with penile pain, erectile dysfunction, and negative impact on quality of life (e.g., emotional distress, depressive symptoms, and relationship difficulties). Other symptoms (e.g., difficulty urinating) may point to a different diagnosis, and are not considered to be a problem associated with Peyronie's disease directly. Patients' symptoms may be self-resolving and may not require treatment. While this disease may compromise sexual function and, therefore, quality of life, it does not impact overall mortality. Treatment with collagenase clostridium histolyticum helps break up the plaques and resolve the deformity.

The American Urological Association (AUA) 2015 guidelines for the management of Peyronie's disease recommends treatment with intraregional collagenase clostridium histolyticum in combination with modeling in patients with stable PD (symptoms have not changed for at least three months), penile curvature >30° and <90°, and intact erectile function (with or without the use of medications), as this is the patient population in which clinical controls were studied . The AUA specifically states that this agent should not be used solely for the treatment of pain or erectile dysfunction due to PD, as this treatment is not without risk (e.g., penile ecchymosis, swelling,

pain, and corporal rupture). In addition, the AUA recommends that the expected results of the treatment be thoroughly discussed with the patients, as typically only a 17 degree curvature reduction is seen, a modest benefit over placebo. There is also no information available regarding the duration of response and long-term effects. The AUA states studies have not been performed in patient populations with hourglass deformity, ventral curvature, calcified plaque, or plaque proximal to the base of the penis. The AUA guidelines include reference to additional exclusion criteria from the IMPRESS trial utilized for FDA approval of Xiaflex for PD. These include curvature less than 30° or greater than 90°, lack of full erectile response to prostaglandin E1 during curvature measurement, and further specifies exclusion criteria of isolated hourglass deformity without curvature.[3]

Xiaflex® has a REMS program due to the risk of corporal rupture. Required components of the program include the following:

- Prescribers must be certified with the program by enrolling and completing training in the administration of treatment for PD.
- Healthcare sites must be certified with the program and ensure that the medication is only dispensed for use by certified prescribers.

REFERENCE/RESOURCES:

1. Xiaflex package insert. Malvern, PA: Auxilium Pharmaceuticals, LLC; 2022 Aug.
2. John's Hopkins Medicine. Dupuytren's Contracture. Available at https://www.hopkinsmedicine.org/health/conditions-and-diseases/dupuytrens-contracture (Accessed September 3, 2024)
3. American Urological Association (AUA). Peyronie's Disease: AUA Guideline, published 2015. Available at https://www.auanet.org/guidelines-and-quality/guidelines/peyronies-disease-guideline (Accessed September 3, 2024).
4. Gliptin D, Coleman S, Hall S, et al. Injectable collagenase Clostridium histolyticum: a new nonsurgical treatment for Dupuytren's disease. https://pubmed.ncbi.nlm.nih.gov/21134613/ (Accessed September 3, 2024).

CODING

Brand Name	Generic Name	Procedure Code
Xiaflex®	collagenase clostridium histolyticum kit	J0775