

Prior Authorization Criteria
Xiaflex (collagenase clostridium histolyticum)

All requests for Xiaflex (collagenase clostridium histolyticum) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **Dupuytren's Contracture** and the following criteria is met:

- Member must be 18 years of age or older
- Documentation the member has one of the following:
 - a finger flexion contracture with a palpable cord of at least one finger (other than the thumb)
 - 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
- Documentation of which cords on which hand are being treated and dates of treatment
- A maximum of two cords in the same hand may be treated during a single treatment visit (all treatment visits must be at least 4 weeks apart)
- A cord may not be injected more than 3 times and at an interval less than 4 weeks
- Must not have received a surgical treatment (e.g. fasciectomy, fasciotomy) on the selected primary joint within 90 days before the first injection
- **Duration of Approval:** 4 months

Coverage may be provided with a diagnosis of **Peyronie's disease** and the following criteria is met:

- Member must be 18 years of age or older
- Must be prescribed by or in consultation with an urologist
- Documentation the member has stable disease defined as symptoms that have remained unchanged for at least 3 months
- Documentation of a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy
- Erectile function must be intact (with or without the use of medications)
- Injections for Peyronie's disease are limited to 4 treatment cycles. (Each cycle consists of 2 Xiaflex injections and one remodeling procedure.)
- **Exclusion criteria:**
 - sexual or erectile dysfunction associated with Peyronie's disease
- **Duration of Approval:** 6 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or



Updated: 7/2023
PARP Approved: 07/2023

peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed.
These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

XIAFLEX (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049

If needed, you may call to speak to a Pharmacy Services Representative. **PHONE:** (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Member ID:	Member weight: Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:
Directions:	Quantity: Refills:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE: _____
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: <input type="checkbox"/> Dupuytren's Contracture <input type="checkbox"/> Peyronie's Disease <input type="checkbox"/> Other: _____	ICD Code:
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For Dupuytren's Contracture, please select all of the following that apply (*please attach supporting documentation*):

- ☐ the member has a finger flexion contracture with a palpable cord of at least one finger (other than the thumb)
- ☐ a positive "table top test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top
- ☐ the flexion deformity is causing functional limitations

Which cord(s) are being treated? _____ Dates of treatment: _____

Was the cord previously treated? ☐ Yes, when: _____ ☐ No

Has the member received a surgical treatment on the selected primary joint 90 days or less before the date of the first scheduled injection? ☐ Yes ☐ No

For Peyronie's Disease:

Does the member have stable disease (symptoms that have remained unchanged for at least 3 months)? please provide documentation ☐ Yes ☐ No

Does the member have a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees? ☐ Yes ☐ No

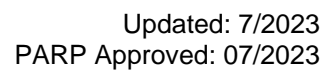
Is erectile function intact (with or without the use of medication)? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

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Prescribing Provider Signature	Date



Updated: 7/2023
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