Gateway Health℠ It's Wholecare.

Updated: 10/2021
PARP Approved: 10/2021

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 a 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 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.

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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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Dupuytren's Contracture ☐ Peyronie's Disease ☐ Other: _____

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

Prescribing Provider Signature	Date