SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

<u>Directions:</u> The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; <u>fax to 1-844-668-1550</u>. No additional phone calls will be necessary if all information (<u>including phone and fax #s</u>) on this form is correct. <u>If information provided is not complete, correct, or legible, authorization can be delayed</u>.

<u>For Medicare Members:</u> Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Xiaflex® (collagenase clostridium histolyticum) (J0775) (Medical)

WENDER & TRESCRIBER	INFORMATION: Authorization may be delayed if incomplete
Member Name:	
Member Sentara #:	Date of Birth:
Prescriber Name:	
	Date:
Office Contact Name:	
Phone Number:	Fax Number:
DEA OR NPI #:	
	horization may be delayed if incomplete.
Drug Form/Strength:	
Dosing Schedule:	Length of Therapy: ICD Code, if applicable:

Recommended Dosage:

• Dupuytren's contracture: Inject 0.58 mg per cord affecting a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint. If contracture persists, finger extension procedure should be performed 24 to 72 hours following injection to facilitate cord disruption. If MP or PIP contracture remains, may reinject cord with a single dose of 0.58 mg 4 weeks following initial injection; injections and finger extension procedures may be administered up to 3 times per cord separated by ~4-week intervals. Note: Up to 2 injections per hand may be used during a treatment; 2 palpable cords affecting 2 joints or 1 palpable cord affecting 2 joints in the same finger may be injected at 2 locations during a treatment. Other palpable cords with contractures of MP or PIP joints may be injected at other treatment visits ~4 weeks apart.

the member's ability to regain maximum function and would not subject the member to severe pain.

• Peyronie's Disease: Inject 0.58 mg into the Peyronie plaque; repeat injection 1 to 3 days later. A penile modeling procedure should be performed 1 to 3 days after the second injection. Administer a second treatment cycle (two 0.58 mg injections and a penile modeling procedure) in ~6 weeks if needed (maximum, 4 treatment cycles [a total of 8 injection procedures and 4 penile modeling procedures]); subsequent treatment cycles should not be administered if the curvature deformity is <15 degrees after a treatment cycle or health care provider determines further treatment is not indicated. The safety of more than 1 treatment course (i.e., 4 treatment cycles) is not known. Note: If more than 1 plaque is present, inject into the plaque causing curvature deformity.

Quantity Limit (max daily dose): 2 vials per 28 days; 1 vial (0.9 mg) = 90 billable units

- Dupuytren's contracture: 180 billable (2 vials) units every 28 days
- Peyronie's Disease: 180 billable units (2 vials) every 42 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Diagnosis: Dupuytren's contracture (ICD M72.0)		
Initial Authorization: 3 months		
	Member has a diagnosis of Duputyren's contracture with a palpable cord	
	Member has a positive Hueston tabletop test defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top	
	Member has a contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint	
	Which hand requires administration of injection?	
	□ Right hand	
	□ Left hand	
	Select <u>ONE</u> of the following to indicate how injection will be administered during the treatment visit (Perform up to two injections in the same hand during a treatment visit):	
	☐ Two palpable cords affecting two joints will be injected	
	 One palpable cord affecting two joints in the same finger will be injected at two locations during the treatment visit 	
	Member is being treated with NO MORE THAN a total of 3 injections per cord	
	Medication will be administered by a healthcare provider	
	Member's contracture causes limitations in function	

(Continued on next page)

Diagnosis: Dupuytren's contracture (ICD M72.0)

Reauthorization: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

NOTE: Medication is eligible for renewal for a maximum of 3 injections per joint/cord

- ☐ Medication has <u>NOT</u> caused toxicity (e.g., anaphylaxis and allergic reactions, abnormal coagulation, tendon ruptures or other serious injury to the injected extremity) or severe adverse events
- ☐ Member has had a response to therapy indicated by the reduction in contracture of the primary joint(s) compared to baseline
- ☐ Member has **NOT** received more than 3 injections per joint/cord

Diagnosis: Peyronie's disease (ICD N48.6)

Initial Authorization: 1 month

- \square Member has a palpable plaque and curvature deformity of > 30 and < 90 degrees at the beginning of therapy
- ☐ Member's curvature causes pain (during erection and/or intercourse)
- ☐ Member is being treated with **NO MORE THAN** 8 injections per plaque
- ☐ Medication will be administered by a healthcare provider
- ☐ Member's plaque does <u>NOT</u> involve the penile urethra

Diagnosis: Peyronie's disease (ICD N48.6)

Reauthorization: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

NOTE: Medication is eligible for renewal for a maximum of 4 total treatment cycles for each plaque causing the curvature deformity

- ☐ Medication has <u>NOT</u> caused toxicity (e.g., anaphylaxis and allergic reactions, abnormal coagulation, tendon ruptures or other serious injury to the penis) or severe adverse events
- ☐ Member has had a response to therapy indicated by the improvement in penile curvature deformity
- ☐ Member has a curvature deformity of at least 15 degrees after the previous treatment cycle(s) which clinically indicated further treatment
- ☐ Member has <u>NOT</u> received more than 4 total treatment cycles for each plaque causing the curvature deformity
- ☐ Member has **NOT** received a collagenase injection for this condition within the past 6 weeks

Medication being provided by: Please check applicable box below.	
	Location/site of drug administration:
	NPI or DEA # of administering location:
	<u>OR</u>
	Specialty Pharmacy – PropriumRx

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

**Use of samples to initiate therapy does not meet step edit/ preauthorization criteria. **

*Previous therapies will be verified through pharmacy paid claims or submitted chart notes. *