XIAFLEX®
collagenase clostridium histolyticum injection 0.9mg

CHART DOCUMENTATION GUIDE

XIAFLEX® (collagenase clostridium histolyticum) is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

This document is provided to help educate healthcare professionals regarding assembling clinical information typically required by payors for the purposes of confirming coverage.

Diagnosis: _____

Date of symptom onset: _____

Penile curvature deformity at start/current: _____

Palpable plaque: ☐

Presence of pain at time of assessment: ☐

Prior treatments: _____

Treatment Cycle Visit 1	Appointment Date: _____
☐ Evaluate patient's penis for appropriate treatment	
☐ Provide patient with copy of XIAFLEX Medication Guide and "What You Need to Know About XIAFLEX Treatment for Peyronie's Disease: A Patient Guide" and urge patient to read it	
☐ Go over Patient Counseling points from the XIAFLEX full Prescribing Information with patient	
☐ Have a discussion with patient about potential adverse reactions and what to do if one or more occur(s)	
☐ Prior to each treatment cycle, inject pharmacologic agent(s) into corpora cavernosa to induce erection (identify specific agent[s] used)	
☐ Prior to each treatment cycle, locate the plaque at the point of maximum concavity (or focal point) in the bend of the penis and mark the point with a surgical marker	
☐ A treatment cycle consists of two XIAFLEX injection procedures and a penile modeling procedure	
☐ Measure and document degree of curvature	
☐ Explain injection protocol to patient	
☐ Allow time for erection to detumesce (the penis should be in a flaccid state before XIAFLEX is injected)	
☐ Reconstitute XIAFLEX per instructions in full Prescribing Information	
☐ If required, administer suitable local anesthetic	
☐ Reconstituted XIAFLEX solution should be clear. Do not use if there is particulate matter and solution is discolored	
☐ Inject XIAFLEX into palpable plaque per the instructions in the Prescribing Information (note the following: injected 0.58 mg XIAFLEX and discarded 0.32 mg). **Do not advance the needle beneath the plaque nor perpendicularly toward the corpora cavernosum**	
☐ Instruct patient to return in 24 to 72 hours for second injection	

Please see information about subsequent XIAFLEX injection and the in-office modeling procedure visits on next page.

INDICATION

XIAFLEX® is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

SELECT IMPORTANT SAFETY INFORMATION FOR XIAFLEX

WARNING: CORPORAL RUPTURE (PENILE FRACTURE) OR OTHER SERIOUS PENILE INJURY IN THE TREATMENT OF PEYRONIE'S DISEASE

Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX-treated patients in clinical studies. In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX-treated patients.

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention.

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX REMS Program.

- **Contraindications:** XIAFLEX is contraindicated in the treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure and in patients with a history of hypersensitivity to XIAFLEX or to collagenase used in any other therapeutic application or application method
- **Corporal Rupture or Other Serious Injury to the Penis:** Injection of XIAFLEX into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis. Cases of localized skin and soft tissue necrosis occurring as sequelae of penile hematoma, some requiring surgical intervention, have been reported post-marketing

Please see additional Important Safety Information on next page.

Click for full Prescribing Information, including Boxed Warning and Medication Guide.

Treatment Cycle Visit 2	Appointment Date: _____
☐ Evaluate patient's penis for appropriate treatment	
☐ Explain injection protocol to patient	
☐ Provide patient with copy of XIAFLEX® (collagenase clostridium histolyticum) Medication Guide and "What You Need to Know About XIAFLEX Treatment for Peyronie's Disease: A Patient Guide" and urge patient to read it	
☐ Have a discussion with patient about potential adverse reactions and what to do if one or more occur(s)	
☐ Reconstitute XIAFLEX per instructions in full Prescribing Information	
☐ If required, administer suitable local anesthetic	
☐ Inject XIAFLEX into palpable plaque 2 to 3 mm apart from the first injection (note the following: injected 0.58 mg XIAFLEX and discarded 0.32 mg)	
☐ Instruct patient to return in 24 to 72 hours for modeling procedure	

Treatment Cycle Visit 3	Appointment Date: _____
☐ Evaluate patient's penis for appropriate treatment	
☐ Explain protocol for modeling procedure	
☐ Inform patient about potential adverse effects of the modeling procedure, what to do if one or more occur(s), and appropriate actions until the next visit	
☐ If required, administer suitable local anesthetic	
☐ Grasp the plaque or indurated portion of the flaccid penis about 1 cm proximal and distal to the injection site, avoiding direct pressure on the injection site	
☐ Using the plaque as a fulcrum point, use both hands to apply firm, steady pressure to elongate and stretch the plaque	
☐ Hold pressure for 30 seconds, then release. Perform 3 times with a 30-second rest period between stretches	
☐ Provide instructions for performing penile modeling at home for 6 weeks following this visit	
☐ Schedule the patient for follow-up in approximately 6 weeks	

IMPORTANT SAFETY INFORMATION FOR XIAFLEX (continued)

- **Hypersensitivity Reactions, Including Anaphylaxis:** In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease, a greater proportion of XIAFLEX-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX injection procedures). The incidence of XIAFLEX-associated pruritus was similar after each injection regardless of the number of injections administered
  - Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. Anaphylaxis was reported in a post-marketing clinical trial in one patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections. The safety of more than one treatment course of XIAFLEX is not known
- **Risk of Bleeding in Patients with Abnormal Coagulation:** In the XIAFLEX controlled trials in Peyronie's disease, 65.5% of XIAFLEX-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis. Patients with abnormal coagulation (except for patients taking low-dose aspirin, eg, up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin, eg, up to 150 mg per day) within 7 days prior to XIAFLEX administration is not known. In addition, it is recommended to avoid use of XIAFLEX in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin)
- **Acute Post-Injection Back Pain Reactions:** Post-marketing reports of acute lower back pain reactions, sometimes accompanied by radiation to the lower extremities, chest and arms, muscle spasms, chest pain, paresthesias, headache, and dyspnea, have been received by patients treated with XIAFLEX for Peyronie's disease. These events can be mild to severe in intensity. The events typically lasted for 15 minutes and typically did not require intervention. Administer the smallest number of treatment cycles necessary to treat the patient's curvature deformity
- **Syncope and Presyncope:** Most, but not all cases of syncope and presyncope in patients with Peyronie's disease, occurred in association with post-injection penile pain and hematoma, penile pain with spontaneous erections, and pain during micturition. These potential triggers suggest a vasovagal mechanism. Make patients aware of the potential symptoms that could trigger syncope and presyncope after treatment with XIAFLEX.
  If presyncopal symptoms occur, patients should remain recumbent until symptoms resolve. Syncope may be associated with bodily injuries, including concussion, head abrasion, and other accidental injuries

Adverse Reactions

Clinical trials

- In the XIAFLEX clinical trials for Peyronie's disease, the most frequently reported adverse drug reactions (≥25%) and at an incidence greater than placebo included: penile hematoma, penile swelling, and penile pain.

Post-marketing experience

- Acute post-injection lower back pain reactions have occurred in close temporal proximity to XIAFLEX treatments
- Cases of localized skin and soft tissue necrosis events as sequelae of penile hematoma, some of which required surgical intervention
- Syncope and presyncope have been reported in men treated with XIAFLEX for Peyronie's disease. Most, but not all cases occurred in the immediate treatment period or within 1-2 days following injection. Bodily injuries associated with the syncopal events have been reported

Click for full Prescribing Information, including Boxed Warning and Medication Guide.

MM-05872/March 2023 www.xiaflex.com 1-800-462-ENDO (3636)