Possible Coding for XIAFLEX® (collagenase clostridium histolyticum) and Related Procedures per Treatment Cycle

Coding is part of the clinical decision and each provider is responsible for selecting the billing codes that most accurately describe the services provided and for adhering to payor guidance. Coding information is subject to change. Using these codes is not a guarantee of payment and does not take the place of professional coding advice.

	VISIT 1		VISIT 2 (24 TO 72 HOURS AFTER VISIT 1)	VISIT 3 (24 TO 72 HOURS AFTER VISIT 2)
	Induce Erection[a]	Administer XIAFLEX® INTO PEYRONIE'S PLAQUE OF FLACCID PENIS	Administer XIAFLEX® INTO PEYRONIE'S PLAQUE OF FLACCID PENIS	Penile Modeling Procedure
ICD-10 Code	N48.6 Peyronie's disease			
CPT Codes	**54235:** Injection of corpora cavernosa with pharmacologic agent(s) (eg, papaverine, phentolamine)	**54200:** Injection procedure for Peyronie's disease	**54200-58[b]:** Injection procedure for Peyronie's disease	
Drug Codes	Physician's discretion	J0775 (represents 0.01 mg of XIAFLEX® [single-use vial])		
		Commercial: Bill as 90 Units[c]	Medicare: Bill as two separate lines *Line 1: J0775 (58 Units*)* *Line 2: J0775 - JW (32 Units*)*	

Abbreviations: ICD–10, International Classification of Diseases–Tenth Revision; CPT, Current Procedural Terminology.
[a]This procedure is performed to induce an erection to determine where to inject XIAFLEX®.
[b]Use of the –58 modifier indicates a staged or related procedure or service by the same physician during the postoperative period.
[c]Or as directed by the insurance plan.
*These amounts are provided as an example of the recommended dose and wastage in accordance with the XIAFLEX® Prescribing Information.

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.

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.

Please see additional Important Safety Information on next page.

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

XIAFLEX®
collagenase clostridium histolyticum

IMPORTANT SAFETY INFORMATION FOR XIAFLEX *(cont)*

- **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
- **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.

Sources:

ICD-10 Code Lookup. Centers for Medicare & Medicaid Services website. https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx. Accessed August 17, 2022.

Global surgery fact sheet. Centers for Medicare & Medicaid Services website. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/GlobalSurgery-ICN907166.pdf. Accessed August 17, 2022.

Optum360® EncoderPro.com. https://www.encoderpro.com/epro/logon.do. Accessed August 17, 2022.

XIAFLEX®
collagenase clostridium histolyticum injection 0.9mg

endo

MM-05782/August 2022 www.xiaflex.com 1-800-462-ENDO (3636)