

Possible Coding for XIAFLEX[®] 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 <i>Line 1: J0775 (58 Units*)</i> <i>Line 2: J0775 - JW (32 Units*)</i>	

Abbreviations: ICD-10, International Classification of Diseases-Tenth Revision; CPT, Current Procedural Terminology.

^aThis procedure is performed to induce an erection to determine where to inject XIAFLEX[®].

^bUse of the -58 modifier indicates a staged or related procedure or service by the same physician during the postoperative period.

^cOr 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 Important Safety Information continued on reverse side.

Please [click here](#) for full Prescribing Information, including Boxed Warning and Medication Guide.

XIAFLEX[®]
collagenase clostridium histolyticum

IMPORTANT SAFETY INFORMATION FOR XIAFLEX® (cont)

- 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
- 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
- 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

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

Please [click here](#) 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 19, 2019.

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