

Instructions for Completing the Prescription and Benefits Investigation Form

XIAFLEX[®]
collagenase clostridium histolyticum

1

Patient Authorization

This section allows the patient to provide written consent for Endo Advantage™ to perform services on his behalf.

2

Texting Opt-in

This section allows the patient to opt in to receive text messages from the specialty pharmacy with updates on his prescription. **Please Note:** In order to receive text messages from CVS Specialty Pharmacy, the mobile phone # must be provided.

4

Ship-to Information

Shipments of XIAFLEX[®] for this patient will be delivered to this practice location.

endo ADVANTAGE Committed to Access
Prescription and Benefits Investigation Form
Phone: 1-800-743-2382 Fax: 1-800-939-3348

1 Please complete this form in its entirety to ensure timely processing of the Benefit Investigation.

I. Patient Authorization to Share Health Information
I have read and understand the Patient Authorization on the back of this form and agree to the terms. I am entitled to a copy of this authorization. This authorization expires 5 years from the date signed below.
A PATIENT SIGNATURE A _____ Date _____ Patient Printed Name _____

II. Opt-in for Text Messages from CVS Specialty Pharmacy
I have read and understand "Opt-in for Text Messages from CVS Specialty Pharmacy" on the back of this form and expressly authorize CVS Specialty Pharmacy ("CVS") and its partners to contact me via text with information about my prescription, such as refill reminders.
B PATIENT SIGNATURE B _____ Date _____ Patient Printed Name _____

Patient Information
3
NOTE: Please provide copy of insurance card[s] along with the information below.
First Name _____ Last Name _____ MI _____ Primary Insurance _____
Address _____ Policy # _____ Group # _____
City _____ State _____ ZIP _____ Provider Services Phone # _____
Mobile Phone # _____ Last 4 #s of SSN _____ Secondary Insurance _____
Email _____ DOB _____ Policy # _____ Group # _____
Provider Services Phone # _____

Physician Ship-to Information
4
Physician Name _____ NPI # _____ DEA # _____
Physician Specialty _____ Tax ID # _____ Medicare PTAN _____
Practice Name _____ XIAFLEX[®] REMS Healthcare Provider Enrollment ID # _____
Practice Ship-to Address _____ XIAFLEX[®] REMS Healthcare Setting Enrollment ID # _____
City _____ State _____ ZIP _____ Contact Person _____
Contact Phone # _____ Fax # _____ Contact Email _____

Clinical Information
5
NOTE: Please submit clinical notes and supporting documentation for the following items along with the form.
Diagnosis Code N48.6 Yes No
Date of Peyronie's disease symptom onset _____ Prior treatment(s) for Peyronie's disease _____
Penile curvature deformity (current degree of curvature) _____ Medication allergies _____
 Palpable plaque Presence of pain during intercourse or erection Anticipated injection date _____

Prescription Information
I authorize CVS Specialty Pharmacy to act as my representative, and on behalf of myself and my patient, to initiate any de minimis authorization processes from applicable health plans, if needed, including the submission of any necessary forms to such health plans.
PRESCRIBER SIGNATURE REQUIRED A (no stamps) _____ Date _____
In New York, please attach all prescriptions on official New York prescription forms. In Iowa, please submit prescriptions electronically to CVS Specialty Pharmacy. In Florida, it may be required that you submit prescriptions electronically. XIAFLEX[®] (collagenase clostridium histolyticum) for injection, 0.9 mg single-use vial
Sig: Inject 0.58 mg into penile plaque 2 times, 1 to 3 days apart, at approximately 6-week intervals (up to 4 cycles)
Dispense: 2 vials Refill: times NDC# 66887-003-01
 Yes No Request syringes for reconstitution and administration, Qty 4 (1-mL, hubless syringe, 0.01-mL graduations, permanently fixed, 27-gauge, 1/2" needle)
I appoint Endo Advantage™ as my agent to convey this prescription to the pharmacy.
PRESCRIBER SIGNATURE REQUIRED B (no stamps) _____ Date _____

Please see Indication and Important Safety Information for XIAFLEX[®] on reverse.
Please see accompanying full Prescribing Information and Medication Guide.

XIAFLEX[®]
collagenase clostridium histolyticum

3

Patient Information

Endo Advantage™ uses this information to research medical and pharmacy coverage for XIAFLEX[®] and related procedures. **Please Note:** In order to receive text messages from CVS Specialty Pharmacy, the mobile phone # must be provided.

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Prescription Information

When signed by the provider, serves as a prescription for XIAFLEX[®].

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](#).

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- **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 ($\geq 25\%$) 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.](#)

XIAFLEX[®]
collagenase clostridium histolyticum injection
0.9mg



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MM-05787/August 2022 www.xiaflex.com 1-800-462-ENDO (3636)