ENDO ADVANTAGE™ BENEFITS INVESTIGATION (BI) RESULTS FORM QUICK REFERENCE GUIDE

How to Read the Benefits Investigation (BI) Results Form

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

Please see Important Safety Information on page 3.
Click for full Prescribing Information, including Boxed Warning and Medication Guide.

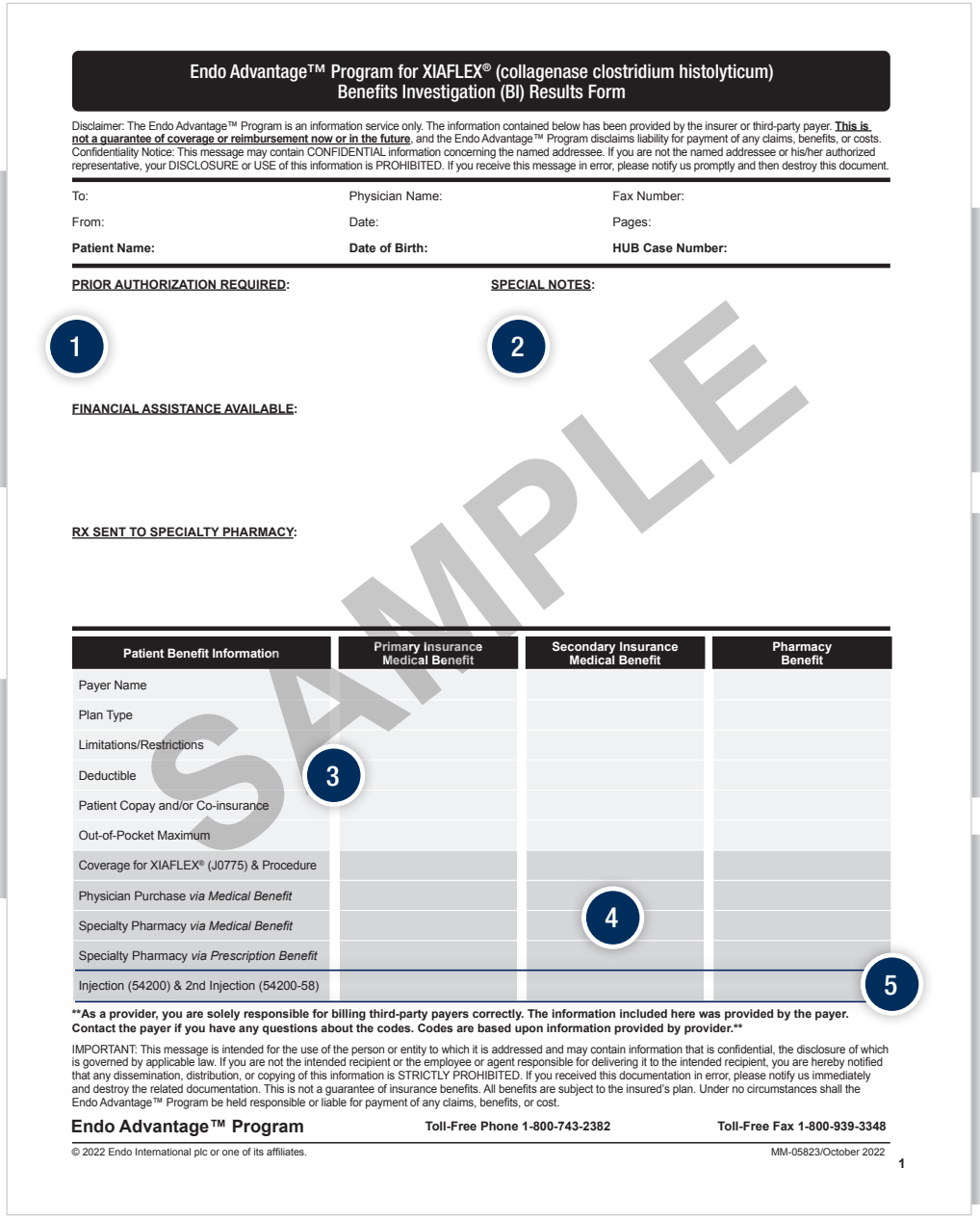
XIAFLEX®
collagenase clostridium histolyticum injection 0.9mg

NOTIFICATION OF PATIENT'S BENEFITS

The Benefits Investigation (BI) Results Form, available from Endo Advantage™, summarizes coverage for an individual patient.

1 IMPORTANT INFORMATION
This is actionable information regarding next steps in drug acquisition, prior authorization, and financial assistance options

3 PLAN COVERAGE
This section provides details about the patient's insurance coverage



Endo Advantage™ Program for XIAFLEX® (collagenase clostridium histolyticum)
Benefits Investigation (BI) Results Form

Disclaimer: The Endo Advantage™ Program is an information service only. The information contained below has been provided by the insurer or third-party payer. **This is not a guarantee of coverage or reimbursement now or in the future**, and the Endo Advantage™ Program disclaims liability for payment of any claims, benefits, or costs. Confidentiality Notice: This message may contain CONFIDENTIAL information concerning the named addressee. If you are not the named addressee or his/her authorized representative, your DISCLOSURE or USE of this information is PROHIBITED. If you receive this message in error, please notify us promptly and then destroy this document.

To:	Physician Name:	Fax Number:
From:	Date:	Pages:
Patient Name:	**Date of Birth:**	**HUB Case Number:**

PRIOR AUTHORIZATION REQUIRED:

SPECIAL NOTES:

1

2

FINANCIAL ASSISTANCE AVAILABLE:

RX SENT TO SPECIALTY PHARMACY:

Patient Benefit Information	Primary Insurance Medical Benefit	Secondary Insurance Medical Benefit	Pharmacy Benefit
Payer Name			
Plan Type			
Limitations/Restrictions			
Deductible			
Patient Copay and/or Co-insurance			
Out-of-Pocket Maximum			
Coverage for XIAFLEX® (J0775) & Procedure			
Physician Purchase *via Medical Benefit*			
Specialty Pharmacy *via Medical Benefit*			
Specialty Pharmacy *via Prescription Benefit*			
Injection (54200) & 2nd Injection (54200-58)			

3

4

5

****As a provider, you are solely responsible for billing third-party payers correctly. The information included here was provided by the payer. Contact the payer if you have any questions about the codes. Codes are based upon information provided by provider.****

IMPORTANT: This message is intended for the use of the person or entity to which it is addressed and may contain information that is confidential, the disclosure of which is governed by applicable law. If you are not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this information is STRICTLY PROHIBITED. If you received this documentation in error, please notify us immediately and destroy the related documentation. This is not a guarantee of insurance benefits. All benefits are subject to the insured's plan. Under no circumstances shall the Endo Advantage™ Program be held responsible or liable for payment of any claims, benefits, or cost.

Endo Advantage™ Program **Toll-Free Phone 1-800-743-2382** **Toll-Free Fax 1-800-939-3348**

MM-05823/October 2022

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2 IMPORTANT INFORMATION
Review this area for additional important information related to the patient's insurance plan or access options

4 COVERAGE FOR XIAFLEX® (J0775)
This section provides details about coverage for XIAFLEX® according to the patient's benefit structures

5 COVERAGE FOR THE INJECTION AND SECOND INJECTION
This section provides details about coverage for the procedures according to the patient's medical coverage

NOTE: Coding is part of the clinical decision. Please use codes that most accurately reflect the procedures performed. Suggestions by Endo Pharmaceuticals Inc. do not guarantee reimbursement or take the place of professional coding advice.

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- **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.

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