endo ADVANTAGE™ Committed to Access

Patient Assistance Program Application

PHYSICIAN INFORMATION

Physician Name _____ Physician Specialty _____

Practice Name _____ Contact Person _____

Practice Address _____

City _____ State _____ ZIP _____

Fax # _____ Phone # _____ Phone Type ☐ Main ☐ Direct ☐ Mobile

Alternate Phone # _____ Contact Email _____

XIAFLEX® Managed Distribution Program Site ID # _____ Product XIAFLEX®

PHYSICIAN CERTIFICATION

My signature below certifies (1) that the person named on this form is my patient and that XIAFLEX® (collagenase clostridium histolyticum) received in response to this application is only for the use of the patient named on this form; (2) that this medication will not be offered for sale, trade, or barter; (3) that no claim for reimbursement of either XIAFLEX® or related medical procedures and services will be submitted to Medicare, Medicaid, or any third party; (4) that XIAFLEX® will not be returned for credit; (5) that Endo USA, Inc. and its agents have the right to contact my patient directly to confirm receipt of XIAFLEX®, and to revise, change, or terminate this program at any time; (6) that to the best of my knowledge my patient meets Endo's criteria for the Endo Advantage™ Patient Assistance Program; and (7) that the information provided in this application is complete and accurate.

Physician Signature _____ Date _____

PATIENT INFORMATION

Last Name _____ First Name _____ MI _____ Date of Birth _____

Address _____

City _____ State _____ ZIP _____

Daytime Phone # _____ Alternate Phone # _____

Total Household Income _____ Total # of Dependents _____

ELIGIBILITY AND TREATMENT INFORMATION

Insurance: Patient is uninsured (no third-party or private insurance) ☐ Yes ☐ No

Residency: US resident or permanent citizen ☐ Yes ☐ No

Diagnosis: Dupuytren's contracture ICD-10 M72.0 ☐ Yes ☐ No

Income documentation attached (1040, 1040EZ, SSI Letter, SSDI, IRS-4506-T, Notarized Letter) ☐ Yes ☐ No

Total number of joints to treat _____

PATIENT CERTIFICATION AND CONSENT

I would like to receive XIAFLEX® at no charge through the Endo Advantage™ Patient Assistance Program. I understand that all the information I provide in connection with this application will be used to determine my eligibility to participate in the Endo Advantage™ Patient Assistance Program.

I certify that I do not have coverage for prescription drugs under Medicare, Medicaid, or any other public or private insurance plan, nor am I able to receive XIAFLEX® under any other assistance program.

I understand that Endo USA, Inc., the sponsor of the Endo Advantage™ Patient Assistance Program, reserves the right to modify or discontinue this program with respect to any patient, or in its entirety, at any time. I also understand that although XIAFLEX® may be given to me at no charge now, this does not mean I will be entitled to receive it at no charge indefinitely.

I consent to the release and disclosure of personal information, including my medical records, name, Social Security number, address, and date of birth to Endo USA, Inc., its agents, distributors, or other designated representatives who may need my personal information to process this application, assure continuity of care, and in order for me to receive XIAFLEX® at no charge. I hereby expressly authorize my physician to release to the Endo Advantage™ Patient Assistance Program all information that may be required in connection with this application. I also authorize the Endo Advantage™ Patient Assistance Program, Endo USA, Inc., and its agents to release medical information and related information to each other in order for me to receive XIAFLEX®. I understand that this information will not be used for any other purpose unless I give written consent, the government requires it, or the Endo Advantage™ Patient Assistance Program removes my name and any other identifying information.

I hereby certify the accuracy of the information submitted on, and in connection with, this application. I also acknowledge that Endo USA, Inc. and its agents have the right to verify my eligibility for the Patient Assistance Program, to audit reported financial and insurance information and medical records, to contact me directly to confirm receipt of XIAFLEX®, and to revise, change, or terminate this program at any time.

Patient Signature _____ Date _____

Endo USA, Inc. reserves the right to make an independent determination of financial and medical need.

Please send this completed form to: Endo Advantage™ Patient Assistance Program
Address: 6000 Park Lane, Pittsburgh, PA 15275
Phone: 1-877-942-3539

Please see Indication and Important Safety Information on next page.

Click for full Prescribing Information, including Medication Guide.

INDICATION

XIAFLEX® is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.

IMPORTANT SAFETY INFORMATION FOR XIAFLEX

- XIAFLEX is contraindicated in patients with a history of hypersensitivity to XIAFLEX or to collagenase used in any other therapeutic application or application method
- In the controlled and uncontrolled portions of clinical trials in Dupuytren's contracture, flexor tendon ruptures occurred after XIAFLEX injection. Injection of XIAFLEX into collagen-containing structures such as tendons or ligaments of the hand may result in damage to those structures and possible permanent injury such as tendon rupture or ligament damage. Therefore, XIAFLEX should be injected only into the collagen cord with a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint contracture, and care should be taken to avoid injecting into tendons, nerves, blood vessels, or other collagen-containing structures of the hand. When injecting a cord affecting a PIP joint of the fifth finger, the needle insertion should not be more than 2 to 3 mm in depth and avoid injecting more than 4 mm distal to the palmar digital crease
- Other XIAFLEX-associated serious local adverse reactions in the controlled and uncontrolled portions of the clinical studies included pulley rupture, ligament injury, complex regional pain syndrome (CRPS), sensory abnormality of the hand, and skin laceration (tear). In a historically controlled post-marketing trial, the incidence of skin laceration (22%) was higher for subjects treated with two concurrent injections of XIAFLEX compared with subjects treated with up to three single injections in the placebo-controlled premarketing trials (9%). Post-marketing cases of skin laceration requiring skin graft after finger extension procedures and local skin and soft-tissue necrosis, some requiring skin grafting, or other surgical interventions including finger amputation have been reported. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required
- Cases of syncope and presyncope have been reported in the post-marketing period in patients treated with XIAFLEX. In most cases in patients with Dupuytren's contracture, the injection procedure, finger extension procedure, or pain following the procedures were reported as potential triggers for the events, suggesting a vasovagal mechanism. Most, but not all, cases occurred in the immediate treatment period (injection or finger extension procedure) or within 1 to 2 days following the injection or finger extension procedure. 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
- In the controlled portions of the clinical trials in Dupuytren's contracture, a greater proportion of XIAFLEX-treated patients (15%) compared to placebo-treated patients (1%) had mild allergic reactions (pruritus) after up to 3 injections. The incidence of XIAFLEX-associated pruritus increased after more XIAFLEX injections in patients with Dupuytren's contracture
- 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
- In the XIAFLEX trials in Dupuytren's contracture, 70% and 38% of XIAFLEX-treated patients developed an ecchymosis/contusion or an injection site hemorrhage, respectively. 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 Dupuytren's contracture, the most common adverse reactions reported in ≥25% of patients treated with XIAFLEX and at an incidence greater than placebo were edema peripheral (eg, swelling of the injected hand), contusion, injection site hemorrhage, injection site reaction, and pain in the injected extremity
- Post-marketing experience – Syncope and presyncope have been reported in patients treated with XIAFLEX. Most, but not all, cases occurred in the immediate treatment period or within 1 to 2 days following injection. Bodily injuries associated with the syncopal events have been reported

Click for full Prescribing Information, including Medication Guide.

XIAFLEX®
collagenase clostridium histolyticum

endo

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