Patient Assistance Program Application

PHYSICIAN INFORMATION

Physician Name _____ Physician Specialty _____

Practice Name _____ Contact Person _____

Practice Address (no PO boxes) _____

City _____ State _____ ZIP _____

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

Alternate Phone # _____ Contact Email _____

REMS 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 Keenova Therapeutics and its agents (collectively, "Keenova") 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 Keenova's criteria for the Keenova™ CARES 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: Peyronie's disease ICD-10 N48.6 ☐ Yes ☐ No

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

PATIENT CERTIFICATION AND CONSENT

I would like to receive XIAFLEX® (collagenase clostridium histolyticum) at no charge through the Keenova™ CARES 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 Keenova™ CARES 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 Keenova, the sponsor of the Keenova™ CARES 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 Keenova, 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 Keenova™ CARES Patient Assistance Program all information that may be required in connection with this application. I also authorize the Keenova™ CARES Patient Assistance Program, Keenova, 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 Keenova™ CARES Patient Assistance Program removes my name and any other identifying information.

I understand that this authorization is voluntary and that if I do not sign it, my ability to obtain treatment from my physician or obtain insurance benefits will not be affected; however, I will not be eligible to receive the services described above. I understand that I may revoke this authorization at any time, to end further use and disclosure of my information, except to the extent that my information has been used or disclosed in reliance upon this authorization, or as permitted by law.

I hereby certify the accuracy of the information submitted on, and in connection with, this application. I also acknowledge that Keenova and its agents have the right to verify my eligibility for the Keenova™ CARES 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 _____

Keenova reserves the right to make an independent determination of financial and medical need.

Please send this completed form to: Keenova™ CARES
Address: 6000 Park Lane, Pittsburgh, PA 15275
Phone: 1-800-743-2382 / Fax: 1-800-939-3348

Please see Indication and Important Safety Information on next page.

Click for full Prescribing Information, including BOXED WARNING and Medication Guide.

INDICATION

XIAFLEX® (collagenase clostridium histolyticum) 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

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
- **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.

XIAFLEX®
collagenase clostridium histolyticum injection 0.9mg

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