RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Xiaflex (collagenase clostridium histolyticum) is used to treat a progressive hand disease known as Dupuytren's contracture, which can affect a person’s ability to straighten and properly use their fingers and as a non-surgical treatment option for men with a bothersome curvature of the penis, a condition known as Peyronie’s disease (1).

Dupuytren’s contracture affects the connective tissue found beneath the skin in the palm of the hand. Too much collagen can build up, forming thick, rope-like cords of tissue that can prevent the fingers from being able to relax and straighten normally (1).

Peyronie’s disease is caused by scar tissue that develops under the skin of the penis. This scar tissue causes an abnormal bend of at least 30 degrees upon erection (1).

Xiaflex is a biologic drug made from the protein product of a living organism. It works by breaking down the excessive buildup of collagen (a structural protein in connective tissue) in the hand and penis (1, 2).

Regulatory Status
FDA-approved indication: Xiaflex is a combination of bacterial collagenases indicated for the treatment of adult patients with Dupuytren’s contracture with a palpable cord and in 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 (2).

Xiaflex has a boxed warning regarding corporal rupture (penile fracture) or other serious penile injury such as severe penile hematoma in the treatment of Peyronie’s disease. The boxed warning also states that Xiaflex is available for treatment of Peyronie’s disease through the Xiaflex REMS program (2).

Xiaflex is contraindicated in the treatment of Peyronie’s plaques that involves the penile urethra due potential risk to this structure (2).

Injections of Xiaflex into tendons, nerves, blood vessels, or other collagen-containing structure
of the hand should be avoided due to the risk of possible permanent injury, such as tendon rupture or ligament damage (2).

Xiaflex is injected directly into the collagen cord of the hand and should only be administered by a health care professional experienced with injections of the hand, because tendon ruptures may occur. Recommended dosing for Dupuytren’s contracture is 0.58 mg per injection, with a max dose of up to three injections per cord with a four week interval between injections (2).

A treatment course for Peyronie’s disease consists of a maximum of four treatment cycles. Each treatment cycle consists of two Xiaflex injection procedures (in which Xiaflex is injected directly into the collagen-containing structure of the penis) and one penile modeling procedure performed by the health care professional. The interval between treatment cycles is approximately six weeks. The treatment course therefore, consists of a maximum of eight injection procedures and four modeling procedures. If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if the health care provider determines that further treatment is not clinically indicated, the subsequent treatment cycles (second or third cycle) should not be administered (2).

The Risk Evaluation and Mitigation Strategy (REMS) program for Xiaflex required by the FDA is intended to help manage known or potential serious risks associated with Xiaflex.

The safety and efficacy of Xiaflex in pediatric patients less than 18 years old has not been established (2).

Summary
Xiaflex is a combination of bacterial collagenases indicated for the treatment of adult patients with Dupuytren’s contracture with a palpable cord and in 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. The Risk Evaluation and Mitigation Strategy (REMS) program for Xiaflex is required by the FDA and is intended to help manage known or potential serious risks associated with Xiaflex as well as ensure the benefits outweigh the risks for each patient. The safety and effectiveness of Xiaflex in pediatric patients less than 18 years old has not been established.
XIAFLEX
(collagenase clostridium histolyticum)

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Xiaflex while maintaining optimal therapeutic outcomes (2).

References