

**XIAFLEX
(collagenase clostridium histolyticum)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Xiaflex (collagenase clostridium histolyticum) is a biologic drug made from a mixture of proteins derived from *Clostridium histolyticum* bacteria. It works by breaking down excessive buildup of collagen, a structural protein in connective tissue. Xiaflex is used in the treatment of Dupuytren's contracture and 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 properly. 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 (2).

Regulatory Status

FDA-approved indications: 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 (1).

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. Because of this risk Xiaflex is only available for treatment of Peyronie's disease through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Xiaflex REMS program (1).

Xiaflex is contraindicated in the treatment of Peyronie's plaques that involves the penile urethra due potential risk to this structure (1).

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 (1).

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In the treatment of Dupuytren's contracture, Xiaflex is injected directly into the collagen cord of the hand and should only be administered by a healthcare professional experienced with injections of the hand, due to the risk of tendon rupture. 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 (1).

Xiaflex for the treatment of Peyronie's disease should be administered by a healthcare professional who is experienced in the treatment of male urological diseases. 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 healthcare 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 healthcare provider determines that further treatment is not clinically indicated, the subsequent treatment cycles (second or third cycle) should not be administered. The safety of more than one treatment course of Xiaflex for Peyronie's disease is not known (1).

The safety and efficacy of Xiaflex in pediatric patients less than 18 years of age have not been established (1).

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 for the treatment of Peyronie's disease 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 of age have not been established (1-2).



**BlueCross.
BlueShield.**

Federal Employee Program.

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

References

1. Xiaflex [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2022.
2. Dupuytren's contracture and Peyronie's disease: Diagnosis and medical management. UpToDate. Accessed on January 23, 2025.