



XIAFLEX® (injectable clostridial collagenase)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

Description:

Xiaflex (injectable clostridial collagenase) is a biologic agent that enzymatically disrupts collagen and has been used as a non-surgical alternative for the treatment of fibroproliferative disorders such as Dupuytren's contracture and Peyronie's disease. Xiaflex has also been investigated for the treatment of adhesive capsulitis.

Fibrotic tissue disorders, characterized by excessive collagen deposits, can affect the musculoskeletal system, causing pain and limitation of movement and reduction of joint range of motion. In Dupuytren's disease, collagen deposition in nodules and cords in the palm and fingers results in pitting of the overlying cutis and flexion contractures. Peyronie's disease is the development of abnormal scar tissue, or plaques, in the tunica albuginea layer of the penis causing distortion, curvature, and pain, usually during erection.



MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 03/05/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

XIAFLEX (injectable clostridial collagenase) (cont.)

Criteria:

See Resources section for FDA-approved dosage.

- FDA-approved dosage of Xiaflex is considered **medically necessary** for the treatment of Dupuytren's contracture in individuals 18 years of age and older with a palpable cord for up to 3 injections per cord at intervals of at least 30 days.
- If benefit coverage for sexual dysfunction is available, FDA-approved dosage of Xiaflex is considered **medically necessary** 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.
- Xiaflex (injectable clostridial collagenase) for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Adhesive capsulitis

Resources:

1. 5.01.19 BCBS Association Medical Policy Reference Manual. Injectable Clostridial Collagenase for Fibroproliferative Disorders. Re-issue date 10/10/2013, issue date 03/11/2010.
2. American Society for Surgery of the Hand. Dupuytren's Disease. 2011.



XIAFLEX (injectable clostridial collagenase) (cont.)

Resources: (cont.)

Xiaflex Package Insert:

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult Dupuytren's contracture with a palpable cord	<p>Xiaflex should be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Xiaflex is administered by intralesional injection.</p> <p>Dosage is 0.58mg per injection. Approximately 24 hours following an injection, perform a finger extension procedure if a contracture persists.</p> <p>Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.</p> <p>Inject only one cord at a time. If a patient has other palpable cords with contractures, inject each cord in sequential order.</p>
Adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy	<p>A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of 2 Xiaflex injection procedures and one penile modeling procedure. The second Xiaflex injection procedure is performed 1 to 3 days after the first. The penile modeling procedure is performed 1 to 3 days after the second injection of the treatment cycle. The interval between treatment cycles is approximately six weeks. The treatment course consists of a maximum of 8 injection procedures and 4 modeling procedures.</p> <p>If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or it is determined that further treatment is not clinically indicated, then the subsequent treatment cycles should not be administered. The safety of more than one treatment course of Xiaflex is not known.</p> <p>Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease, Xiaflex is available only through the XIAFLEX REMS Program. Required components of the program include the following:</p> <ol style="list-style-type: none">1. Prescribers must be certified with the program by enrolling and completing training in the administration of Xiaflex treatment for Peyronie's disease.2. Healthcare sites must be certified with the program and ensure that Xiaflex is only dispensed for use by certified prescribers.