

DEAR PHYSICIAN: This letter is being provided as a sample to help you with your payor interactions concerning reimbursement for the administration of XIAFLEX[®] (collagenase clostridium histolyticum). Use of this document does not guarantee coverage or reimbursement. As a health care professional, you are solely responsible for providing accurate information to third-party payors. If there is any information in this document that does not accurately reflect your practices, it should be modified to appropriately represent your particular circumstances.

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

IMPORTANT SAFETY INFORMATION

- 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 MP or 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 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%)
- 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 study 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
- 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 $\geq 25\%$ 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

Please see [full Prescribing Information](#) and [Medication Guide](#).

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October 2014 XDC-00952

[Date]

[Insurance contact name]

[Insurance contact title]

[Name of insurance company]

[Insurance street address]

[City, state, ZIP code]

Re: Denied Injection Claim Appeal Request for XIAFLEX[®] (collagenase clostridium histolyticum)

Patient name: [First and last name]

Patient date of birth: [XX/XX/XXXX]

SS #: [XXX-XX-XXXX]

Insurance ID #: [XXXXXXXXXXXXXXXXXX]

Group #: [XXXXXXX]

Claim #: [XXXXXXXX]

Dear [Insurance contact name]:

I am writing on behalf of my patient, [patient's name], to request reconsideration of a denied claim for XIAFLEX. XIAFLEX is an injection and is the only nonsurgical therapy approved by the FDA for the treatment of adult patients with Dupuytren's contracture with a palpable cord. Up to two cords in the same hand may be injected at a single treatment visit. If a patient has other cords with contractures, those cords are injected at another treatment visit. XIAFLEX was provided to [patient's name] on [date of service] to treat [his/her] Dupuytren's contracture.

Dupuytren's contracture is a benign fibroproliferative condition characterized by excessive collagen deposition causing abnormal thickening of the fascia. This can result in the formation of a ropelike cord beneath the skin of the palm, stretching from the palm into the fingers. Gradually, these cords may thicken and shorten causing the fingers to bend into the palm, resulting in permanent joint contractures.

You have indicated that XIAFLEX is not eligible for coverage under the patient's health insurance plan due to [reason for denial from explanation of benefits]. [If due to injection of 2 cords simultaneously, include following line:] On October 20, 2014, the FDA expanded the XIAFLEX Prescribing Information for injection of up to 2 cords in the same hand at a single treatment visit.

After a thorough review of the patient's history and condition, I have reconfirmed that treatment with XIAFLEX was medically necessary for [patient's name]. To further support the medical necessity of this patient's treatment with XIAFLEX, I am including information on the patient's history and diagnosis, as well as additional information on the patient's condition.

[Reasons why XIAFLEX was prescribed, information on patient's condition, specific joint(s) affected, number of cords and degrees of contracture for metacarpophalangeal/proximal interphalangeal joint release; patient's medical records, impact on range of motion, and information regarding published data on the drug's clinical utility].

Based on the preceding facts, I believe treatment with XIAFLEX was appropriate and medically necessary for this patient. I would appreciate reconsideration of this claim.

XIAFLEX is billed using the following codes:

Product Code (J code) designated by the Centers for Medicare & Medicaid Services

J0775: represents 0.01 mg of XIAFLEX

Procedure Codes (CPT® codes) designated by the American Medical Association (AMA)

20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture)

20527-59*: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture)—distinct procedural service

26341: Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord (10-day global)

29130[†]: Application of finger splint; static

26341-59*: Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord (10-day global)—distinct procedural service

29130-59*[†]: Application of finger splint; static—distinct procedural service

**The codes used to describe single-cord treatment of adult patients with Dupuytren's contracture with a palpable cord may also be used to describe treatment for up to 2 joints/cords in the same hand. Modifiers may be necessary to ensure services are processed and paid correctly.*

[†]Application of finger splint should be used only when the procedure is performed in a physician's office.

Modifier -59 Distinct Procedural Service for Medicare. Under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-Evaluation and Management (E/M) services performed on the same day. Refer to full AMA coding guidance. Modifier -59 is necessary for the injection procedure.

Modifier -51 Multiple Procedures for Commercial Payors. When multiple procedures, other than E/M services, Physical Medicine and Rehabilitation services or provision of supplies (eg, vaccines), are performed at the same session by the same individual, the primary procedure or service may be reported as listed. The additional procedure(s) or service(s) may be identified by appending modifier -51 to the additional procedure or service code(s). Note: This modifier should not be appended to designated "add-on" codes.

If you have any further questions, please feel free to contact my office to discuss this case. Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name and credentials]

[Title]

[Name of practice]

[Street address]

[City, state, ZIP code]

[Phone number]

Enclosures:

[Patient medical records/chart notes]

[XIAFLEX® (collagenase clostridium histolyticum) full Prescribing Information]