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. For example, coding is a clinical decision and Endo provides codes for physician reference only. As a healthcare 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.

INDICATION

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

IMPORTANT SAFETY INFORMATION FOR XIAFLEX

- 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 metacarpophalangeal (MP) or proximal interphalangeal (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 clinical 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%). Post-marketing cases of skin laceration requiring skin graft after finger extension procedures and local skin and soft-tissue necrosis, some requiring skin grafting, or other surgical interventions including finger amputation have been reported. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required

- Cases of syncope and presyncope have been reported in the post-marketing period in patients treated with XIAFLEX. In most cases in patients with Dupuytren's contracture, the injection procedure, finger extension procedure, or pain following the procedures were reported as potential triggers for the events, suggesting a vasovagal mechanism. Most, but not all, cases occurred in the immediate treatment period (injection or finger extension procedure) or within 1 to 2 days following the injection or finger extension procedure. 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

- 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 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

- 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 ≥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

- Post-marketing experience – Syncope and presyncope have been reported in patients treated with XIAFLEX. Most, but not all, cases occurred in the immediate treatment period or within 1 to 2 days following injection. Bodily injuries associated with the syncopal events have been reported

Click for full Prescribing Information and Medication Guide.

MM-05778/August 2022 www.XIAFLEX.com 1-800-462-ENDO (3636)

[Date]

[Insurance contact name]
[Insurance contact title]
[Name of insurance company]
[Insurance street address]
[City, State ZIP]

Re: Denied XIAFLEX® (collagenase clostridium histolyticum) Finger Extension Procedure Claim Appeal Request

Patient name: **[First and last name]**
Patient date of birth: **[XX/XX/XXXX]**
SS #: **[XXX-XX-XXXX]**
Insurance ID #: **[XXXXXXXXXXXXXXX]**
Group #: **[XXXXXXX]**
Claim #: **[XXXXXXXX]**

Dear **[Insurance contact name]**:

I am writing to you on behalf of my patient, **[patient's name]**, to request reconsideration of your denial of a claim for the follow-up/finger extension procedure following XIAFLEX® administration.

XIAFLEX® is indicated for adult patients with Dupuytren's contracture with a palpable cord. Treatment with XIAFLEX® involves the administration of an injection by a healthcare provider into the Dupuytren's cord and a follow-up visit for a finger extension procedure.

XIAFLEX® was provided to **[patient's name]** on **[date of service]** to treat **[his/her]** Dupuytren's contracture with a palpable cord. Per the XIAFLEX® Prescribing Information, at the follow-up visit approximately 24 to 72 hours after the injection(s), if a contracture remains, perform a passive finger extension procedure on each treated joint to facilitate cord disruption.

This letter and the enclosed documents provide the necessary documentation to support coverage and payment of this claim.

The subsequent finger extension procedure is described as follows:

Finger Extension Procedure per XIAFLEX® (collagenase clostridium histolyticum) Prescribing Information

1. **At the follow-up visit approximately 24 to 72 hours after the injection(s)**, if a contracture remains, perform a passive finger extension procedure on each treated joint (as described below) to facilitate cord disruption. If two joints in one finger were treated, perform the finger extension procedure on the affected metacarpophalangeal (MP) joint before performing the finger extension procedure on the affected proximal interphalangeal (PIP) joint.

2. Local anesthesia may be used. Avoid direct pressure on the injection site as it will likely be tender. Care should be taken during release of contracture, as some patients may experience skin splitting. If this occurs, cover the area with gauze and apply gentle pressure until bleeding stops. Standard wound care with regular dressings should be applied.

3. While the patient's wrist is in the flexed position, apply moderate stretching pressure to the injected cord by extending the finger for approximately 10 to 20 seconds. For cords affecting the PIP joint, perform the finger extension procedure when the MP joint is in the flexed position.

4. If the first finger extension procedure does not result in disruption of the cord, a second and third attempt can be performed at 5- to 10-minute intervals. However, no more than 3 attempts per joint are recommended to disrupt a cord.

5. If the cord has not been disrupted after 3 attempts, a follow-up visit may be scheduled in approximately 4 weeks. If, at that subsequent visit, the contracted cord persists, an additional XIAFLEX® injection with finger extension procedure(s) may be performed.

6. Following the finger extension procedure(s), fit patient with a splint and provide instructions for use at bedtime for up to 4 months to maintain finger extension. Also, instruct the patient to perform finger extension and flexion exercises several times a day for several months.

I have enclosed a copy of the detailed procedure reports describing the administration of XIAFLEX® and the extension of the affected finger(s) for **[patient's name]**. The detailed report includes: **[a description of my professional time spent on this procedure, the effort and skill required to perform the service, time, and involvement of additional clinical staff, and the procurement of necessary equipment and supplies for the procedure.]**

This procedure has been assigned the following billing codes:

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

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

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

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.[1]

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.[2]

Thank you for your consideration. If you have any questions about this patient or would like additional information to assist your review of this claim, please contact me at **[contact information].**

Sincerely,

[Physician's name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State ZIP]

[Phone number]

Enclosures:

[Patient medical records/chart notes]

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

References: 1. Centers for Medicare and Medicaid Services. Proper use of modifiers 59 & –X{EPSU}. https://www.cms.gov/files/document/proper-use-modifiers-59-xepsu.pdf. Accessed August 9, 2022. **2.** OPTUM306. Modifier 51 Coding website. https://www.encoderpro.com/epro/allModifiersHandler.do?_k=101*0&_a=listRelated&menu=4. Accessed August 9, 2022.