## XIAFLEX® (collagenase clostridium histolyticum) **Coding Scenario 2: Modifier Required** Hometown Hospital 123 Main Street STATEMENT COVERS PERIOD Anycity, Anystate 12345 5 FED. TAX NO. Doe, John Q. Anycity, Anystate 12345 10 BIRTHDATE 14 TYPE 15 SRC 16 DHR 17 STAT VALUE CODES AMOUNT b 42 REV. CD. 43 DESCRIPTION 44 HCPCS / RATE / HIPPS CODE 46 SERV. UNITS 47 TOTAL CHARGES 45 SERV. DATE 48 NON-COVERED CHARGES 0250 Drugs and Biologicals .10775 092021 180 -XXX XX 0342 Therapeutic Procedure 20527 092021 XXX XXX 0342 Therapeutic Procedure 20527 092021 XXX XX 0342 Therapeutic Procedure 26341 092021 1 XXX XXX 0342 Therapeutic Procedure 26341 092021 XXX XX It is possible that any given payor may accept or require a different coding paradigm for same-day, dual cord treatments such as the use of modifier 51, 76, 59, or XS (which is effective Jan. 1, 2015, and This value indicates 2 vials of may replace modifier 59) and/or billing service individually on separate line items. Please contact the 90 units each. XIAFLEX® Reimbursement Helpline (1-877-942-3539) or the payor's Provider Service Representative to acquire more information on coding guidance. SAMPLE 1450 FORM TREATMENT BILLING WHEN TREATING 2 CORDS/JOINTS Based on prior policy, this sample represents how your Medicare Administrative Contractor (MAC) is likely to require completion of claim forms for J0775, and the CPT® codes 20527 and 26341. This sample form is not intended to replace or modify your MAC's policy, and use of this form does not guarantee payment or take the place of professional coding advice. Coding is part of the clinical decision, and each provider is responsible for selecting the billing codes that most accurately describe the services provided and for adhering to all payor guidance. Information is subject to change. Please refer to the policy on the MAC's website. This sample claim form does not represent any clinical or treatment recommendation. 8 INSURED'S NAME 59 P.REL 60 INSURED'S UNIQUE ID 61 GROUP NAME 62 INSURANCE GROUP NO. 63 TREATMENT AUTHORIZATION CODES 64 DOCUMENT CONTROL NUMBER 65 EMPLOYER NAME M72.0 OTHER PROCEDU RINCIPAL PROCEDI 76 ATTENDING QUAL NPI AST FIRST QUAL AST FIRST 80 REMARKS 78 OTHER QUAL 79 OTHER QUAL LAST FIRST HE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF. OMB APPROVAL PENDING UB-04 CMS-1450 NUBC National Uniform LIC9213257

## **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
- <u>Post-marketing experience</u> 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

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