

## XIAFLEX® (collagenase clostridium histolyticum) Coding Scenario 2: Modifier Required

Hometown Hospital
123 Main Street Anycity, Anystate 12345
PATIENT NAME Doe, John Q.
PATIENT ADDRESS Anycity, Anystate 12345
BIRTHDATE SEX DATE ADMISSION TYPE SRC DHR STAT CONDITION CODES ACCT STATE
OCCURRENCE DATE OCCURRENCE DATE OCCURRENCE DATE OCCURRENCE DATE OCCURRENCE SPAN THROUGH OCCURRENCE SPAN THROUGH
VALUE CODES AMOUNT VALUE CODES AMOUNT VALUE CODES AMOUNT
REV. CD. DESCRIPTION HCPCS / RATE / HIPPS CODE SERV. DATE SERV. UNITS TOTAL CHARGES NON-COVERED CHARGES
0250 Drugs and Biologicals J0775 092021 180 XXX XX
0342 Therapeutic Procedure 20527 092021 1 XXX XX
0342 Therapeutic Procedure 20527 092021 1 XXX XX
0342 Therapeutic Procedure 26341 092021 1 XXX XX
0342 Therapeutic Procedure 26341 092021 1 XXX XX

It is possible that any given payor may accept or require a different coding paradigm for same-day, dual treatments such as the use of modifier 51, 76, 59, or XS (which is effective Jan. 1, 2015, and will replace modifier 59) and/or billing service individually on separate line items. Please contact the FLEX® Reimbursement Helpline (1-877-942-3539) or the payor's Provider Service Representative to obtain more information on coding guidance.

This value indicates 2 vials of 90 units each.

## 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.

INSURED'S NAME PREL INSURED'S UNIQUE ID GROUP NAME INSURANCE GROUP NO.
TREATMENT AUTHORIZATION CODES DOCUMENT CONTROL NUMBER EMPLOYER NAME
M72.0
ADMIT DX PATIENT REASON DX PPS CODE ECI ATTENDING NPI QUAL LAST FIRST OPERATING NPI QUAL LAST FIRST OTHER NPI QUAL LAST FIRST
REMARKS

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MM-05790/August 2022

## 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  $\geq 25\%$  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
- 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

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