XIAFLEX® (collagenase clostridium histolyticum) **Coding Scenario 1: No Procedure Modifier Required** CARRIER HEALTH INSURANCE CLAIM FORM **Medicare Part B Claims** APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12 PICA FECA BLK LUNG (ID#) (For Program in Item 1) 1. MEDICARE MEDICAID TRICARE CHAMPVA OTHER 1a. INSURED'S I.D. NUMBER (ID#/DoD#) (Member ID#) (ID#) (Medicare#) (Medicaid#) 123-45-6789A 2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE 4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John Q 10 | 19 | 1935 5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED 7 INSURED'S ADDRESS (No. Street) 1212 Main St. Self X Spouse Child Same 8. RESERVED FOR NUCC USE STATE CITY STATE PATIENT AND INSURED INFORMATION XX **Any City** ZIP CODE TELEPHONE (Include Area Code) ZIP CODE TELEPHONE (Include Area Code) XXXXX 9. OTHER IN **SAMPLE 1500 FORM** a. OTHER INS TREATMENT BILLING **AARP** b. RESERVE WHEN TREATING 2 CORDS/JOINTS c. RESERVE Based on prior policy, this sample represents how your Medicare Administrative Contractor (MAC) is likely to require d. INSURANC completion of claim forms for J0775, and the CPT® codes 20527 and 26341. This sample form is not intended to d 9d. replace or modify your MAC's policy, and use of this form does not guarantee payment or take the place of professional uthorize 12. PATIENT to process 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 SIGNED change. Please refer to the policy on the MAC's website. This sample claim form does not represent any clinical or PATION 14. DATE OF MM | D treatment recommendation. ICES 17 NAME OF 17b. NPI FROM 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC 20. OUTSIDE LAB? \$ CHARGES YES 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) 22. RESUBMISSION ICD Ind. ORIGINAL REF. NO. M72.0 D. E. l FΙ G. 24. A. DATE(S) OF SERVICE D. PROCEDURES, SERVICES, OR SUPPLIES RENDERING PLACE OF DIAGNOSIS MM CPT/HCPCS \$ CHARGES PROVIDER ID. # SERVICE POINTER These amounts represent 58 03 11 J0775 XXX XX 10 116 NP units per cord/joint (total of 116 units) and wastage of 32 JW 10 11 J0775 XXX XX NP units per cord/joint (total of 3 20527 XXX XX NPI 64 units) and are provided as 10 an example of the 26341 XXX XX NPI 10 Use JW modifier to indicate recommended dose and how much drug is wasted wastage in accordance with NPI from single-use vials. the XIAFLEX® Prescribing Information. NPI 25. FEDERAL TAX I.D. NUMBER SSN EIN 27. ACCEPT ASSIGNMENT? 29. AMOUNT PAIC 30. Rsvd for NUCC Use 26. PATIENT'S ACCOUNT NO. YES XXXX XX XXXX XX 31. SIGNATURE OF PHYSICIAN OR SUPPLIER 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) DATE APPROVED OMB-0938-1197 FORM 1500 (02-12) NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE

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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