

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

Please see additional Important Safety Information on next page. Click for full Prescribing Information, including Medication Guide.



POSSIBLE CODES FOR TREATING A SINGLE JOINT AT 1 VISIT

XIAFLEX® (collagenase clostridium histolyticum) is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.

XIAFLEX® Billing for Healthcare Provider Offices, Hospital Outpatient Departments, and Ambulatory Surgery Centers

	XIAFLEX® Possible Coding					
	ICD-10-CM	Procedure Code	Drug Code			
	M72.0 Palmar fascial fibromatosis [Dupuytren]	20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture)	J0775 (represents 0.01 mg of XIAFLEX®)			
Injection			Commercial: Bill as 90 units	Medicare: Bill as two separate lines Line 1: J0775 (58 units†) Line 2: J0775 (32 units†) and apply the JW modifier		
Follow-up Visit	M72.0 Palmar fascial fibromatosis [Dupuytren]	26341: Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord (10-day global) AND	N/A			
		29130*: Application of finger splint; static				

^{*}Application of finger splint should be used only when the procedure is performed in a physician's office.

NOTE: Coding is part of the clinical decision. Please use codes that most accurately reflect the procedures performed. Suggestions by Endo do not guarantee reimbursement or take the place of professional coding advice.

SOURCES: ICD-10 code lookup. Centers for Medicare & Medicaid Services website. https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx. Accessed August 13, 2022.

Billing and coding guidelines. Centers for Medicare and Medicaid Services website. https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/30153_18/l30153_ms007_cbg_010112.pdf. August 13, 2022.

Correct coding for finger splint applications. Optum360® EncoderPro.com. https://www.encoderpro.com/epro/logon.do. Accessed August 13, 2022.

IMPORTANT SAFETY INFORMATION FOR XIAFLEX (cont)

• 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

POSSIBLE CODES FOR TREATING 2 JOINTS IN THE SAME HAND IN 1 VISIT

• The codes used to describe single joint treatment of adult patients with Dupuytren's contracture with a palpable cord may also be used to describe treatment of up to 2 joints in the same hand during a treatment visit

XIAFLEX® Billing for Healthcare Provider Offices, Hospital Outpatient Departments, and Ambulatory Surgery Centers

	XIAFLEX® Possible Coding					
	ICD-10-CM	Procedure Code		Drug Code		
Injection	M72.0 Palmar fascial fibromatosis [Dupuytren]	20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture) Bill as 2 units OR Two separate lines of 1 unit Line 1: 1 unit Line 2: 1 unit and apply the most appropriate modifier	J0775 (represents 0.01 mg of XIAFLEX®)			
			Commercial: Bill as 180 units	Medicare: Bill as two separate lines Line 1: J0775 (116 units†) Line 2: J0775 (64 units†) and apply the JW modifier		
Follow-up Visit	M72.0 Palmar fascial fibromatosis [Dupuytren]	26341: Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord (10-day global) Bill as 2 units OR Two separate lines of 1 unit Line 1: 1 unit Line 2: 1 unit and apply the most appropriate modifier AND 29130*: Application of finger splint; static	N/A			

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 and/or billing service individually on separate line items. Please contact the XIAFLEX® Reimbursement Helpline (877-942-3539) or the payor's Provider Service Representative to acquire more information on coding guidance.

NOTE: Coding is part of the clinical decision. Please use codes that most accurately reflect the procedures performed. Suggestions by Endo do not guarantee reimbursement or take the place of professional coding advice.

SOURCES: CPT® is a registered trademark of the American Medical Association

Billing and coding guidelines. Centers for Medicare and Medicaid Services website. https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/30153_18/l30153_ms007_cbg_010112.pdf. Accessed August 13, 2022. Correct coding for finger splint applications. Optum360® EncoderPro.com. https://www.encoderpro.com/epro/logon.do. Accessed August 13, 2022.

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[†]These amounts are provided as an example of the recommended dose and wastage in accordance with the XIAFLEX® Prescribing Information.

^{*}Application of finger splint should be used only when the procedure is performed in a physician's office.

[†]These amounts represent 58 units per cord/joint (total of 116 units) and wastage of 32 units per cord/joint (total of 64 units) and are provided as an example of the recommended dose and wastage in accordance with the XIAFLEX® Prescribing Information.

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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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