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Endo Pharmaceuticals Inc. created this handbook for office administration to provide support for product acquisition and reimbursement as you use XIAFLEX® (collagenase clostridium histolyticum), the only FDA-approved, nonsurgical treatment for adult patients with Dupuytren’s contracture with a palpable cord. Up to 2 palpable cords affecting 2 joints in the same hand may be injected or 1 palpable cord affecting 2 joints in the same finger may be injected at 2 locations during a treatment visit. During the follow-up visit (approximately 24 to 72 hours after the injection), a finger extension procedure may be necessary to help break the cord.1

This kit contains information needed to utilize the support resources offered for XIAFLEX®. It includes benefits investigation forms, information about the drug acquisition process, and an overview of financial assistance options for patients. This kit also contains a fax cover sheet, a coding table, and sample claim forms designed to help you access XIAFLEX® for your appropriate patients and help to submit claims correctly.

Reimbursement experts are available to answer questions and help you with the acquisition and reimbursement process. We encourage you to take advantage of these support offerings for XIAFLEX®. Please refer to pages 20-21 for more information.

XIAFLEX® PRODUCT INFORMATION

XIAFLEX® is the only FDA-approved, nonsurgical treatment for adult patients with Dupuytren’s contracture with a palpable cord.1

• XIAFLEX® contains purified collagenase clostridium histolyticum, consisting of 2 microbial collagenases that hydrolyze collagen.1

• Injection of XIAFLEX® into a Dupuytren’s cord, which is composed mostly of collagen, may result in enzymatic disruption of the cord.1

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 injuring 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 palynex 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), conduction, injection site hemorrhage, injection site reaction, and pain in the injected extremity.

• In the 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.

Please see the accompanying full Prescribing Information, including Medication Guide.
SIX STEPS TO HELP STREAMLINE THE XIAFLEX® REIMBURSEMENT PROCESS

1. Identify potential candidates
   - Identify eligible patients
     - XIAFLEX® (collagenase clostridium histolyticum) is indicated for adults with Dupuytren’s contracture with a palpable cord
     - Some patients may be ineligible for surgery or would prefer an in-office procedure
   - Speak with your appropriate patients about XIAFLEX® as a treatment option

2. Verify insurance benefits
   - Endo Advantage™ can help you determine a patient’s coverage, out-of-pocket costs, prior authorization (PA) requirements, if applicable, and drug acquisition options
     - Financial assistance may be available for those patients who qualify

3. Obtain XIAFLEX®
   - There are 2 options for obtaining XIAFLEX® (subject to payor requirements)
     - Buy-and-Bill: Purchase XIAFLEX® from a Specialty Distributor and receive reimbursement from the payor after XIAFLEX® is administered
     - Specialty Pharmacy assignment of benefits: Obtain XIAFLEX® through a Specialty Pharmacy that will bill the payor for XIAFLEX®
   - For more information on the steps in the drug acquisition process and a list of specialty pharmacies and distributors that dispense XIAFLEX®, turn to the acquisition section of this guide on page 12

4. Schedule patient
   - Schedule patient injection visit
     - The Specialty Pharmacy or Distributor will work with your practice to coordinate a delivery date with the patient’s scheduled visit

5. Treat patient
   - Perform the XIAFLEX® procedure
   - Schedule a follow-up visit (approximately 24 to 72 hours after the injection), where a finger extension procedure will be performed if a contracture persists

6. File claim
   - Submit the claim; the following resources are available to help:
     - Your Field Reimbursement Manager
       - Can review your claims for completeness and provide suggested codes
     - Endo Advantage™ at 877-XIAFLEX (877-942-3539)
       - Can help monitor claims to confirm payor processing and payment
       - Can provide templates for appeals in case a XIAFLEX® claim is denied

For vials obtained through the Specialty Pharmacy, it is recommended that you acquire XIAFLEX® prior to scheduling the patient.

Please see Important Safety Information on page 3.
Please see the accompanying full Prescribing Information, including Medication Guide.
PATIENT BENEFIT COVERAGE INFORMATION

INSURANCE BENEFIT VERIFICATION CHECKLIST

COVERAGE

- Is XIAFLEX® (collagenase clostridium histolyticum) covered under this patient’s health insurance plan?
- Is XIAFLEX® covered under the patient’s medical or pharmacy benefit?
- Is XIAFLEX® covered in the desired setting of care?
- Does the insurer mandate any special distribution requirements for coverage (eg, Specialty Pharmacy)?
- What are the patient’s out-of-pocket costs for XIAFLEX®?
- Is the patient eligible for:
  - The XIAFLEX® Copay Assistance Program (for commercially insured patients)?
  - The Patient Assistance Program (for uninsured patients)?
- Does the patient have an annual copay, deductible, or lifetime maximum? If yes, has this been met?

For assistance in determining coverage availability and prior authorization requirements for a particular patient, complete the Prescription and Benefits Investigation Form and fax it to Endo Advantage™ at 1-877-909-2337.

Our XIAFLEX® Copay Assistance Program isn’t the only way we’re trying to help make treatment more affordable for your eligible patients. To find out about other options for financial support, call 1-866-585-5591.

INSTRUCTIONS FOR COMPLETING THE PRESCRIPTION AND BENEFITS INVESTIGATION FORM

ACCESS PREFERENCES

Please choose your preferred method for receiving XIAFLEX®

PATIENT INFORMATION

Endo Advantage™ will use this information to research medical and pharmacy coverage for XIAFLEX® and related procedures, triage prescriptions to a Specialty Pharmacy, as appropriate, and verify the need for PA

SHIP-TO INFORMATION

Shipments of XIAFLEX® for this patient will be delivered to this practice location

Rx INFORMATION

When completed, this section serves as a prescription for XIAFLEX®

Please see Important Safety Information on page 3.
Please see the accompanying full Prescribing Information, including Medication Guide.

For live support from our trained specialists, call Endo Advantage™ at 877-XIAFLEX (877-942-3539), Monday through Friday, 9:00 AM to 8:00 PM ET. For general, non-patient-specific questions about coverage and PA, please contact your Field Reimbursement Manager.
NOTIFICATION OF PATIENT’S BENEFITS

The Benefits Investigation (BI) Results Form, available from Endo Advantage™, summarizes coverage for an individual patient.

1. BENEFITS
   This table summarizes the results of the investigation of the patient’s insurance coverage. This is not a guarantee of reimbursement.

2. PATIENT DETAILS
   Endo Advantage™ will provide confirmation of the number of joints treated.

3. BILLING GUIDELINES
   This section provides guidelines for XIAFLEX® billing. As a provider, you are solely responsible for billing third-party payors correctly.

4. COVERAGE FOR XIAFLEX® (J0775)
   This section provides details about coverage for XIAFLEX® with each access method.

5. ADDITIONAL INFORMATION
   Review this area for information about the next steps in the drug acquisition process.

6. COVERAGE FOR THE INJECTION AND FINGER MANIPULATION
   You may use the suggested codes* shown in this section to bill for the injection and finger manipulation procedure of XIAFLEX®.

7. IMPORTANT INFORMATION
   This message is intended for the use of the person or entity to which it is addressed and may contain information that is confidential, privileged, or otherwise protected from disclosure. If you are not the intended recipient, any dissemination, distribution, or copying of this information is strictly prohibited. If you received this documentation in error, please notify us immediately and destroy the related documentation. This is not a guarantee of insurance benefits. All benefits are subject to the insured’s plan. Under no circumstances shall the Endo Advantage™ Program be held responsible or liable for the disclosure of which is governed by applicable law. If you are not the intended recipient or the employee or agent responsible for delivering it, the disclosure of which is governed by applicable law. If you are not the intended recipient or the employee or agent responsible for delivering it.

Please see Important Safety Information on page 3. Please see the accompanying full Prescribing Information, including Medication Guide.

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

FOR UNINSURED PATIENTS

Endo Pharmaceuticals Inc. offers a Patient Assistance Program (PAP) that provides XIAFLEX® (collagenase clostridium histolyticum) to eligible patients without health insurance benefits who meet specific program criteria, including income levels. Patients should call 1-866-585-5591 to learn more about their eligibility for the Patient Assistance Program (PAP).

PATIENT ELIGIBILITY REQUIREMENTS INCLUDE:

• Receiving or received XIAFLEX® for an approved indication and in a manner consistent with the instructions for administration of XIAFLEX®
• Uninsured or have insurance that is not provided by Medicare, Medicare Prescription Drug Benefit plans, Medicare Advantage, Veterans Affairs (VA), Medicaid, or similar federal or state programs and the offer is not otherwise prohibited by law
• 18 years of age or older
• Patients who have paid or are obligated to pay out-of-pocket costs for a dose of XIAFLEX®
• Patient has not used this program within the last 30 days

No other purchase is necessary to receive this offer. Restrictions apply. See full Terms and Conditions at XIAFLEX.com.

*Based on analysis of claims filed September 2011 through March 2018.

PROGRAM DETAILS:

• The program may cover up to $1200 of your patient’s out-of-pocket costs for each vial of XIAFLEX®
• The XIAFLEX® Copay Card is a multiuse card, so it may be used multiple times by the same patient, up to the $1200 limit per vial
• Other costs such as office visits or injection procedure costs are not covered by the XIAFLEX® Copay Program
• Copay Program reimbursement is subject to verification of eligibility by Endo at its sole discretion, as well as all the terms and conditions of the XIAFLEX® Copay Program, which can be found at XIAFLEX.com
• Patients who participate in Medicare, Medicaid, or other state or federally funded programs, or who reside in states where this offer is prohibited by law, are not eligible for the XIAFLEX® Copay Program

If your office uses a Specialty Distributor (Besse Medical) to obtain XIAFLEX®, remind your eligible patients to complete the Copay Reimbursement Form. Your office then submits the completed form, along with Explanation of Benefits or the patient’s receipt, similar to how you bill for a secondary insurance, to determine the amount that will be reimbursed and the amount your patient may owe for XIAFLEX®.

• The Copay Reimbursement Form is available at XIAFLEX.com

If your office works with a Specialty Pharmacy (CVS Specialty) to acquire XIAFLEX®, the Copay Program will automatically be applied for all eligible patients.

Please see Important Safety Information on page 3. Please see the accompanying full Prescribing Information, including Medication Guide.
## XIAFLEX® ACQUISITION

### OBTAINING XIAFLEX® (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM) FROM A SPECIALTY DISTRIBUTOR OR A SPECIALTY PHARMACY

<table>
<thead>
<tr>
<th>Specialty Distributor (Buy-and-Bill)</th>
<th>Specialty Pharmacy (Assignment of Benefits)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Provider’s practice purchases XIAFLEX® prior to the procedure</td>
<td>• Provider’s practice orders XIAFLEX® from a Specialty Pharmacy</td>
</tr>
<tr>
<td>• Provider submits a claim to the patient’s insurer for the drug and the physician services</td>
<td>• Specialty Pharmacy ships XIAFLEX® to provider’s office and <strong>bills the insurance plan directly for the drug</strong></td>
</tr>
<tr>
<td>• Provider bills the patient’s insurer for the physician services</td>
<td>• Provider bills the patient’s insurer for the physician services</td>
</tr>
</tbody>
</table>

#### Description
- **Payer**
  - Medicare Part B
  - Many commercial payors
  - Some state Medicaid programs

#### Features
- **Payer**
  - Many commercial payors
  - Most state Medicaid programs

- **Features**
  - Just-in-time shipping eliminates the need to hold inventory
  - The distributor may offer up to 90 days to pay for the order

- **Features**
  - No upfront purchase of XIAFLEX®
  - The Specialty Pharmacy will check patient benefits, help manage the PA process (with your support), and manage claim filing **for the drug**

- **Features**
  - Provider does not bill for the drug (but bills for the physician services)

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## SPECIALTY DISTRIBUTOR (BUY-AND-BILL) ACQUISITION METHOD

### HEALTHCARE PROVIDER (HCP) BILLS FOR DRUG AND PROFESSIONAL SERVICES

#### STEP 1
HCP selects an Endo-contracted Specialty Distributor

#### STEP 2
**Endo Advantage™** verifies patient’s insurance benefits

#### STEP 3
Upon approval, HCP contacts Specialty Distributor and purchases XIAFLEX®

#### STEP 4
Specialty Distributor ships drug to HCP

#### STEP 5
HCP administers drug, bills payor (for drug and procedure), and pays Specialty Distributor

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Always check patient benefits prior to obtaining XIAFLEX®.

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**Please see Important Safety Information on page 3.**
**Please see the accompanying full Prescribing Information, including Medication Guide.**

Insurers may require you to use a specific acquisition method. For information on a particular insurer, call **Endo Advantage™** at 877-XIAFLEX (877-942-3539), Monday through Friday, from 9:00 AM to 8:00 PM ET, or contact your Field Reimbursement Manager.
When your signed prescription is forwarded to a Specialty Pharmacy, either directly by your office or through Endo Advantage™ under your direction, the receiving Specialty Pharmacy will initiate its process to dispense XIAFLEX® (collagenase clostridium histolyticum). That process will include the following key steps:

**WHAT TO EXPECT FROM THE SPP**

### Acknowledgment of prescription receipt
- The pharmacy will acknowledge initial receipt of your prescription within 24 hours via fax.

### Perform a benefits investigation
- The pharmacy will begin an internal benefits investigation of the patient’s benefits. The results of this benefits investigation will be communicated to you via fax within 24 hours of completion of this process.

### Provide updates on the prescription status
- The pharmacy should provide periodic updates on the status of the prescription; however, this will vary between pharmacies. It is always recommended that your office contact the specific pharmacy directly with any questions regarding the status of the prescription.

### Contact the patient
- The pharmacy will directly contact the patient with the results of its benefits investigation, ask the patient to accept the prescription, and make arrangements to collect any copay or co-insurance.

### Schedule XIAFLEX® shipment with your office
- The pharmacy will coordinate with your office to schedule the initial XIAFLEX® product shipment date and any subsequent refills.

### Inquire about a refill
- The pharmacy will communicate with your office approximately 14 days after dispensing the initial prescription to inquire about the necessity of a refill. Please make sure to clearly indicate 1 or 2 vials.*

*Injection and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.

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**SPECIALTY PHARMACY PROVIDER (SPP) ACQUISITION METHOD**

**HCP BILLS ONLY FOR PROFESSIONAL SERVICES**

**STEP 1**
HCP submits Prescription and Benefits Investigation Form to Endo Advantage™ for benefit verification. Then, the HCP may send the form directly to the appropriate SPP.
- **Note:** Please make sure to clearly indicate 1 or 2 vials on form.

**STEP 2**
SPP verifies patient’s insurance benefits and identifies any PA requirements and patient financial responsibilities.

**STEP 3**
SPP notifies patient of any financial obligations (copayment/co-insurance) and asks him or her to accept the Rx order.

**STEP 4**
SPP bills payer for drug and bills patient for any copayment or co-insurance.

**STEP 5**
SPP coordinates with HCP to schedule drug shipment.

**STEP 6**
SPP dispenses drug for individual patient with prescription label attached and ships drug to HCP site.

**STEP 7**
HCP administers drug and bills payer for physician services.

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Please see Important Safety Information on page 3. Please see the accompanying full Prescribing Information, including Medication Guide.
PRODUCT ACQUISITION

SPECIALTY DISTRIBUTOR

When a practice obtains XIAFLEX® (collagenase clostridium histolyticum) from a Specialty Distributor, the practice pays for the drug and then bills the insurance plan directly for both the drug and the procedure.

Besse Medical
1-800-543-2111 (phone)
1-800-543-8695 (fax)
Besse.com

SPECIALTY PHARMACY

When a practice obtains XIAFLEX® from a Specialty Pharmacy, the pharmacy bills the insurance plan directly for the drug and the practice bills the insurance plan only for physician services.

CVS Specialty
1-855-534-8323 (phone)
1-888-418-7246 (fax)
CVSspecialty.com

SUCCESSFULLY NAVIGATE XIAFLEX® BILLING AND CLAIMS WITH HELP FROM ENDO

OFFICE MANAGEMENT TOOLS AND TEMPLATE LETTERS ARE AVAILABLE FROM YOUR FIELD REIMBURSEMENT MANAGER OR ENDO ADVANTAGE™:

- Sample letter of medical necessity
- Sample appeal letters for denied injection and finger extension procedure claims (available digitally)

The materials included in this kit will help you incorporate XIAFLEX® into your practice and interact with payors.

If you are unsure about which XIAFLEX® access option may be best for your patients and your practice, ask your Sales Professional or call Endo Advantage™ at 877-XIAFLEX (877-942-3539).

Please see Important Safety Information on page 3.
Please see the accompanying 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**

<table>
<thead>
<tr>
<th>XIAFLEX® Possible Coding</th>
<th>ICD-10-CM</th>
<th>Procedure Code</th>
<th>Drug Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection</td>
<td>M72.0</td>
<td>20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren’s contracture)</td>
<td>J0775 (represents 0.01 mg of XIAFLEX®)</td>
</tr>
<tr>
<td>Commercial:</td>
<td></td>
<td>Bill as 90 units</td>
<td></td>
</tr>
<tr>
<td>Follow-up Visit</td>
<td>M72.0</td>
<td>26341: Manipulation, palmar fascial cord (ie, Dupuytren’s contracture), post enzyme injection (eg, collagenase), single cord (10-day global) AND 29130*: Application of finger splint; static</td>
<td>N/A</td>
</tr>
<tr>
<td>Commercial:</td>
<td></td>
<td>Bill as 180 units</td>
<td></td>
</tr>
</tbody>
</table>

*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.

**SOURCES:**

### 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**

<table>
<thead>
<tr>
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</tr>
<tr>
<td>Commercial:</td>
<td></td>
<td>Bill as 2 units OR Two separate lines of 1 unit</td>
<td></td>
</tr>
<tr>
<td>Follow-up Visit</td>
<td>M72.0</td>
<td>26341: Manipulation, palmar fascial cord (ie, Dupuytren’s contracture), post enzyme injection (eg, collagenase), single cord (10-day global) AND 20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren’s contracture)</td>
<td>N/A</td>
</tr>
<tr>
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| Injection               | M72.0     | 20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren’s contracture) | J0775 (represents 0.01 mg of XIAFLEX®) |
| Commercial:             |           | Bill as 2 units OR Two separate lines of 1 unit |           |
| Follow-up Visit         | M72.0     | 26341: Manipulation, palmar fascial cord (ie, Dupuytren’s contracture), post enzyme injection (eg, collagenase), single cord (10-day global) AND 20527: Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren’s contracture) | N/A |
| Commercial:             |           | Bill as 180 units |           |

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 Endo Advantage™ (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.

**SOURCES:**

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

**NOTE:** These amounts are provided as an example of the recommended dose and wastage in accordance with the XIAFLEX® Prescribing Information.

**SOURCES:**

Please see Important Safety Information on page 3.

Please see the accompanying full Prescribing Information, including Medication Guide.
DEDICATED SUPPORT

YOUR SALES PROFESSIONAL IS YOUR PRIMARY RESOURCE FOR INFORMATION AND PROCESS SUPPORT RELATED TO ACQUIRING XIAFLEX®.

TO ADDRESS CASE-SPECIFIC CODING, BILLING, AND REIMBURSEMENT QUESTIONS, YOUR SALES PROFESSIONAL CAN REFER YOU TO YOUR FIELD REIMBURSEMENT MANAGER.

Your Field Reimbursement Manager is ready to help you with:

- Coverage and logistical questions
- Product access options
- Coding questions
- Patient access resources

ENDO PHARMACEUTICALS INC. IS COMMITTED TO HELPING PATIENTS ACCESS XIAFLEX®

ENDO ADVANTAGE™ IS ALSO AVAILABLE TO PROVIDE ANSWERS TO YOUR REIMBURSEMENT QUESTIONS

For live support from our trained helpline specialists, call Endo Advantage™ at 877-XIAFLEX (877-942-3539), Monday through Friday, 9:00 AM to 8:00 PM ET.

Please see Important Safety Information on page 3. Please see the accompanying full Prescribing Information, including Medication Guide.
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 presyncope 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 trials in Dupuytren’s contracture, 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.

Please see the accompanying full Prescribing Information, including Medication Guide.
