



XIAFLEX® HANDBOOK FOR OFFICE ADMINISTRATION

Using XIAFLEX® in Your Office —
Planning and Preparation for Reimbursement

Please see [Indication and Important Safety Information](#).
Click for full [Prescribing Information](#) and [Medication Guide](#).

XIAFLEX®
collagenase clostridium histolyticum

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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 page [11](#) for more information.

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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 collagen¹
- Injection of XIAFLEX® into a Dupuytren’s cord, which is composed mostly of collagen, may result in enzymatic disruption of the cord¹

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
- 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

Click for full [Prescribing Information](#) and [Medication Guide](#).



Product not actual size.



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

Always check patient benefits prior to obtaining XIAFLEX®

- 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 [7](#)

4

Schedule patient

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

NOTIFICATION OF PATIENT’S BENEFITS

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

1 IMPORTANT INFORMATION
This is actionable information regarding next steps in drug acquisition, prior authorization, and financial assistance options

3 PLAN COVERAGE
This section provides details about the patient's insurance coverage

Endo Advantage™ Program for XIAFLEX® (collagenase clostridium histolyticum)
Benefits Investigation (BI) Results Form

Disclaimer: The Endo Advantage™ Program is an information service only. The information contained below has been provided by the insurer or third-party payer. **This is not a guarantee of coverage or reimbursement now or in the future.** and the Endo Advantage™ Program disclaims liability for payment of any claims, benefits, or costs. Confidentiality Notice: This message may contain CONFIDENTIAL information concerning the named addressee. If you are not the named addressee or his/her authorized representative, your DISCLOSURE or USE of this information is PROHIBITED. If you receive this message in error, please notify us promptly and then destroy this document.

To: Physician Name: Fax Number:
From: Date: Pages:
Patient Name: Date of Birth: HUB Case Number:

PRIOR AUTHORIZATION REQUIRED: SPECIAL NOTES:

1 FINANCIAL ASSISTANCE AVAILABLE: 2

RX SENT TO SPECIALTY PHARMACY:

Patient Benefit Information	Primary Insurance Medical Benefit	Secondary Insurance Medical Benefit	Pharmacy Benefit
Payer Name			
Plan Type			
Limitations/Restrictions			
Deductible			
Patient Copay and/or Co-insurance			
Out-of-Pocket Maximum			
Coverage for XIAFLEX® (J0775) & Procedure			
Physician Purchase via Medical Benefit			
Specialty Pharmacy via Medical Benefit			
Specialty Pharmacy via Prescription Benefit			
Injection (20527) & Finger Manipulation (26341)			

As a provider, you are solely responsible for billing third-party payers correctly. The information included here was provided by the payer. Contact the payer if you have any questions about the codes.

IMPORTANT: This message is intended for the use of the person or entity to which it is addressed and may contain information that is confidential, 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 to the intended recipient, you are hereby notified that 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 payment of any claims, benefits, or cost.

Endo Advantage™ Program Toll-Free Phone 1-800-743-2382 Toll-Free Fax 1-800-939-3348
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2 IMPORTANT INFORMATION
Review this area for additional important information related to the patient's insurance plan or access options

4 COVERAGE FOR XIAFLEX® (J0775)
This section provides details about coverage for XIAFLEX® according to the patient's benefit structures

5 COVERAGE FOR THE INJECTION AND FINGER MANIPULATION
This section provides details about coverage for the procedures according to the patient's medical coverage

SAMPLE BENEFITS INVESTIGATION (BI) RESULTS FORM

All information is for illustrative purposes only.

Endo Advantage™ Program for XIAFLEX® (collagenase clostridium histolyticum)
Benefits Investigation (BI) Results Form

Disclaimer: The Endo Advantage™ Program is an information service only. The information contained below has been provided by the insurer or third-party payer. **This is not a guarantee of coverage or reimbursement now or in the future.** and the Endo Advantage™ Program disclaims liability for payment of any claims, benefits, or costs. Confidentiality Notice: This message may contain CONFIDENTIAL information concerning the named addressee. If you are not the named addressee or his/her authorized representative, your DISCLOSURE or USE of this information is PROHIBITED. If you receive this message in error, please notify us promptly and then destroy this document.

To: Office Manager Physician Name: Dr John Doe Fax Number: (XXX) XXX-XXXX
From: Endo Advantage™ Date: XX/XX/XXXX Pages: 1
Patient Name: John Doe Date of Birth: XX/XX/XXXX HUB Case Number: XXXX-XXXX

PRIOR AUTHORIZATION REQUIRED: YES SPECIAL NOTES:

A prior authorization (PA) is required for both the drug and the procedure. The PA can be initiated by calling (XXX) XXX-XXXX.

FINANCIAL ASSISTANCE AVAILABLE: YES
Patient may be eligible for copay assistance. For more info, please call (XXX) XXX-XXXX.

RX SENT TO SPECIALTY PHARMACY: NO
Covered for Buy-and-Bill access or Specialty Pharmacy access. For Buy-and-Bill, please contact <Wholesaler Name> at (XXX) XXX-XXXX.
For Specialty Pharmacy, please fax Rx to <Specialty Pharmacy Name> at (XXX) XXX-XXXX.

Patient Benefit Information	Primary Insurance Medical Benefit	Secondary Insurance Medical Benefit	Pharmacy Benefit
Payer Name	<Payer Name>	<Payer Name>	<Payer Name>
Plan Type	Commercial	Commercial	Commercial
Limitations/Restrictions	Covered with Restrictions	Covered	Covered
Deductible	\$500 (\$150 met)	No Deductible Applies	No Deductible Applies
Patient Copay and/or Co-insurance	20%	No Copay Applies	\$150
Out-of-Pocket Maximum	\$1000 (\$150 met)	No OOP Applies	No OOP Applies
Coverage for XIAFLEX® (J0775) & Procedure	--	--	--
Physician Purchase via Medical Benefit	Prior Auth Required	No Restrictions	--
Specialty Pharmacy via Medical Benefit	Prior Auth Required	No Restrictions	--
Specialty Pharmacy via Prescription Benefit	--	--	No Restrictions
Injection (20527) & Finger Manipulation (26341)	Prior Auth Required	No Restrictions	--

As a provider, you are solely responsible for billing third-party payers correctly. The information included here was provided by the payer. Contact the payer if you have any questions about the codes.

IMPORTANT: This message is intended for the use of the person or entity to which it is addressed and may contain information that is confidential, 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 to the intended recipient, you are hereby notified that 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 payment of any claims, benefits, or cost.

Endo Advantage™ Program Toll-Free Phone 1-800-743-2382 Toll-Free Fax 1-800-939-3348
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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.

Please see Indication and Important Safety Information.
Click for full Prescribing Information and Medication Guide.



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).

Form titled 'Patient Assistance Program Application' with sections: PHYSICIAN INFORMATION, PHYSICIAN CERTIFICATION, PATIENT INFORMATION, ELIGIBILITY AND TREATMENT INFORMATION, PATIENT CERTIFICATION AND CONSENT. Includes fields for physician details, patient demographics, insurance status, and signatures.

Please see Indication and Important Safety Information.
Click for full Prescribing Information and Medication Guide.

1 PHYSICIAN CERTIFICATION
You should carefully read this section before signing the completed form

2 ELIGIBILITY AND TREATMENT INFORMATION
The information provided in this section will be used to confirm the patient's eligibility. Eligible patients may receive free product through the XIAFLEX® Patient Assistance Program

3 PATIENT CERTIFICATION AND CONSENT
Patients should carefully read this section before signing the completed form

~88% OF ELIGIBLE PATIENTS SHOULD PAY \$0 OUT OF POCKET FOR XIAFLEX®2*

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.

*Most eligible patients with commercial insurance plans should pay a \$0 copay for XIAFLEX®. Predictions based on historical analysis of claims filed September 2022 through August 2023.

PROGRAM DETAILS:

- Other costs, such as office visits or injection procedure costs, are not covered by the XIAFLEX® Copay Assistance Program
• The XIAFLEX® Copay Assistance 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 Assistance 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 Assistance Program

Two orange callout boxes: 'If your office uses a Specialty Distributor (Besse Medical) to obtain XIAFLEX®, remind your eligible patients to complete the Copay Reimbursement Form.' and 'If your office works with a Specialty Pharmacy (CVS Specialty Pharmacy) to acquire XIAFLEX®, the XIAFLEX® Copay Assistance Program will automatically be applied for all eligible patients.'



XIAFLEX® ACQUISITION

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

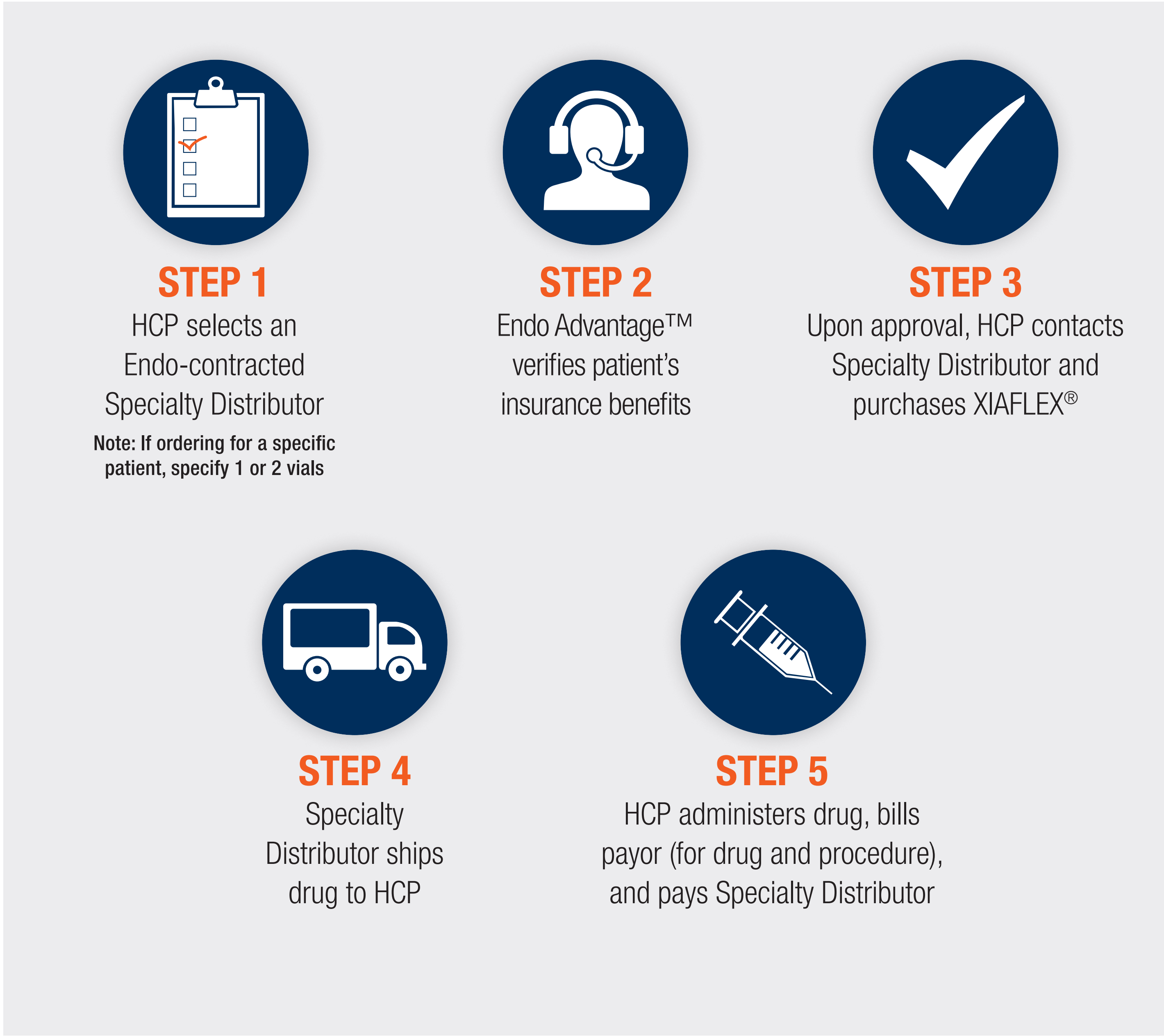
	Specialty Distributor (Buy-and-Bill)	Specialty Pharmacy (Assignment of Benefits)
Description	<ul style="list-style-type: none">• Provider’s practice purchases XIAFLEX® prior to the procedure• Provider submits a claim to the patient’s insurer for the drug and the physician services	<ul style="list-style-type: none">• Provider’s practice orders XIAFLEX® from a Specialty Pharmacy• Specialty Pharmacy ships XIAFLEX® to provider’s office and <i>bills the insurance plan directly for the drug</i>• Provider bills the patient’s insurer for the physician services
Payor	<ul style="list-style-type: none">• Medicare Part B• Many commercial payors• Some state Medicaid programs	<ul style="list-style-type: none">• Many commercial payors• Most state Medicaid programs
Features	<ul style="list-style-type: none">• Just-in-time shipping eliminates the need to hold inventory• The distributor may offer up to 90 days to pay for the order	<ul style="list-style-type: none">• No upfront purchase of XIAFLEX®• The Specialty Pharmacy will check patient benefits, help manage the PA process (with your support), and manage claim filing <i>for the drug</i>• Provider does not bill for the drug (but bills for the physician services)

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.

Please see [Indication and Important Safety Information](#).
Click for full [Prescribing Information](#) and [Medication Guide](#).

SPECIALTY DISTRIBUTOR (BUY-AND-BILL) ACQUISITION METHOD

HEALTHCARE PROVIDER (HCP) BILLS FOR DRUG AND PROFESSIONAL SERVICES

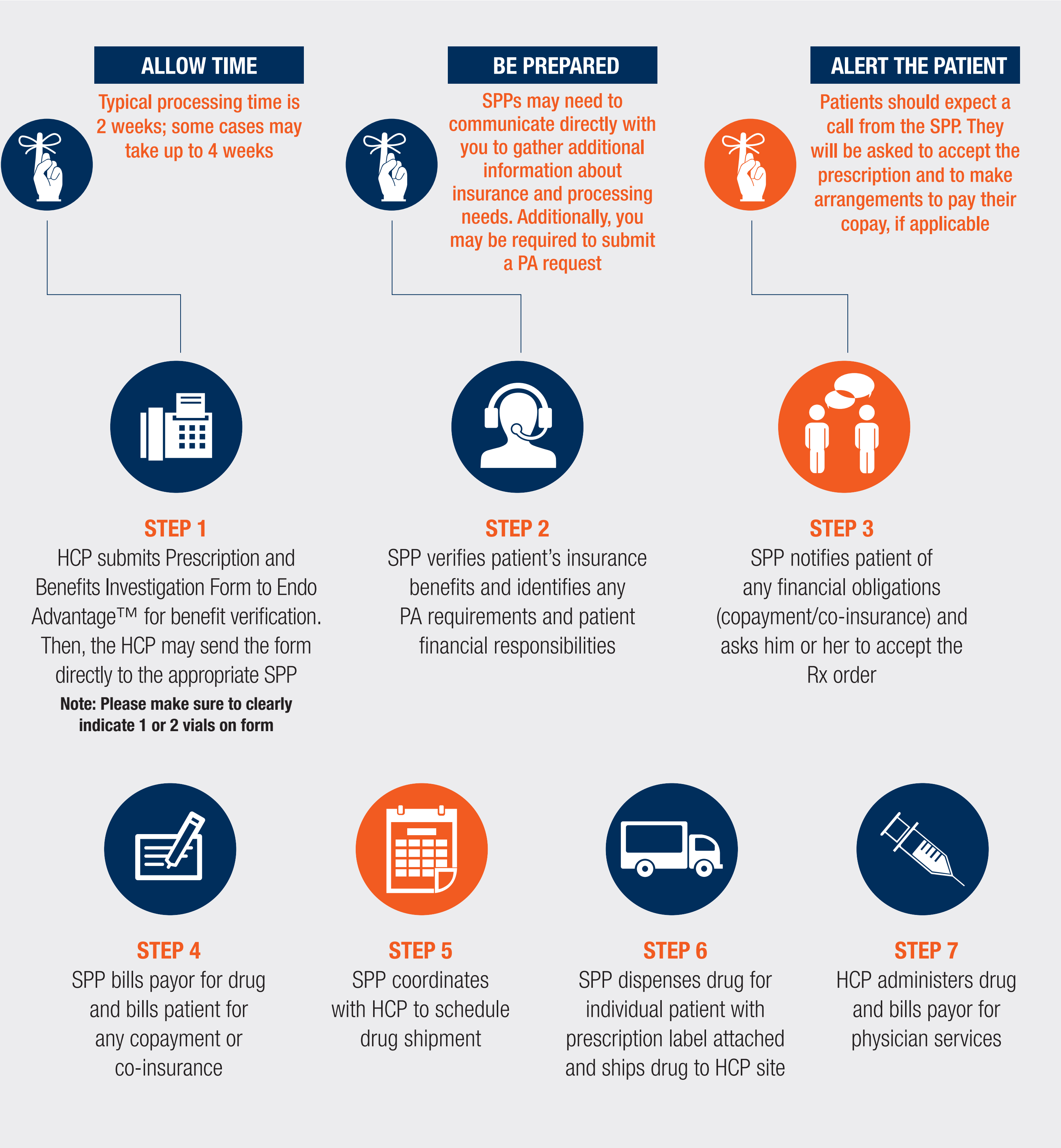


Always check patient benefits prior to obtaining XIAFLEX®.

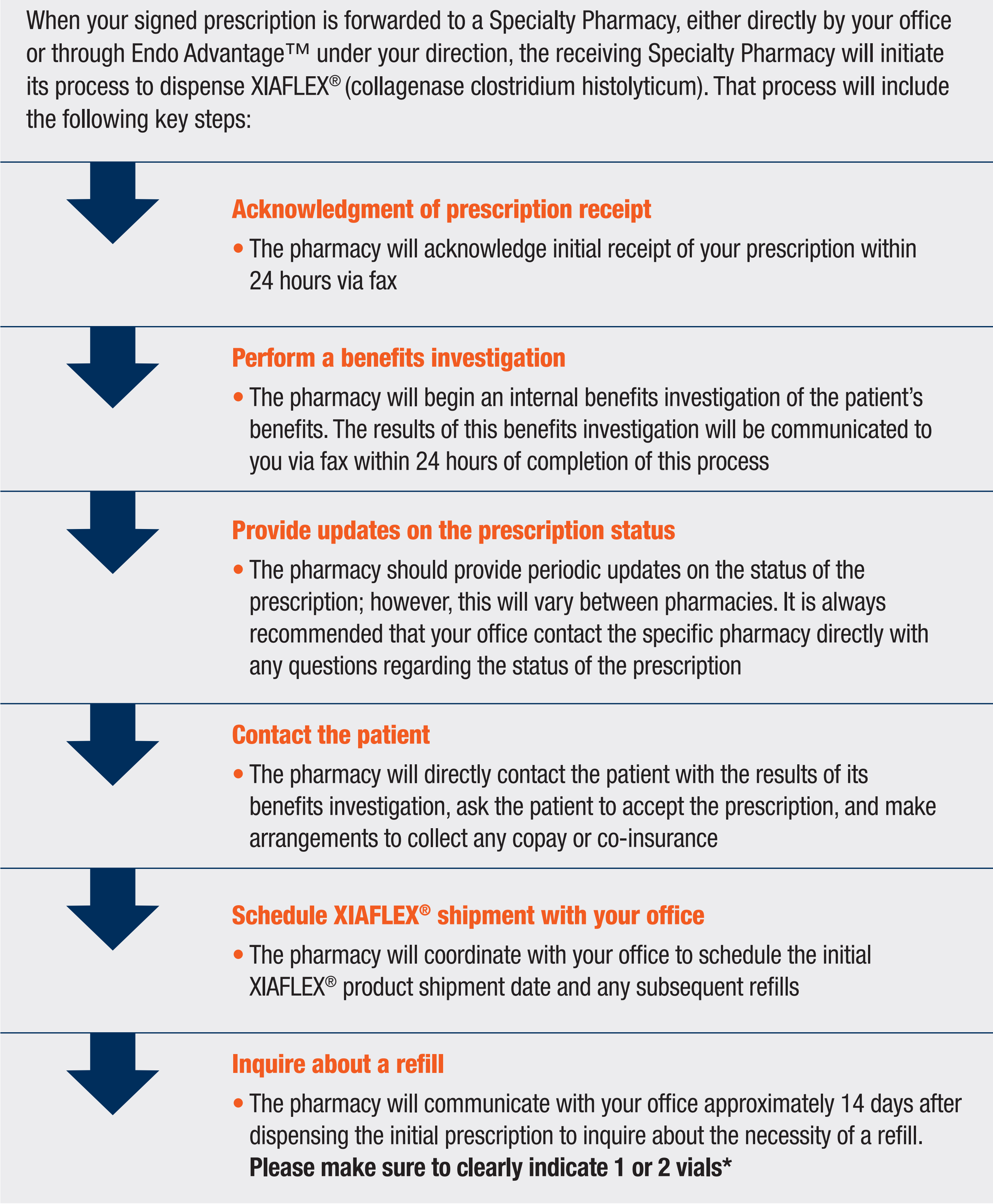


SPECIALTY PHARMACY PROVIDER (SPP) ACQUISITION METHOD

HCP BILLS ONLY FOR PROFESSIONAL SERVICES



WHAT TO EXPECT FROM THE SPP



*Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.¹

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 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 Pharmacy
1-844-343-4221 (phone)
1-877-733-3194 (fax)
CVSspecialty.com

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 [Indication and Important Safety Information](#).
Click for full [Prescribing Information](#) and [Medication Guide](#).

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.

[Date]

[Insurance contact name]
[Insurance contact title]
[Name of insurance company]
[Insurance street address]
[City, state, ZIP code]

Re: Letter of Medical Necessity for XIAFLEX® (collagenase clostridium histolyticum)

Patient name: [First and last name]
Patient date of birth: [XX/XX/XXXX]
SS #: [XXX-XX-XXXX]
Insurance ID #: [XXXXXXXXXXXXXXX]
Group #: [XXXXXXXXXX]

Dear [Insurance contact name]:

This letter provides clinical justification for [patient's name] to receive up to two injections in the same hand with the potential of up to 3 injections per cord, at approximately 4-week intervals, of XIAFLEX® for the treatment of [his/her] Dupuytren's contracture with a palpable cord.

XIAFLEX® is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. Up to two cords in the same hand may be injected at a treatment visit. Two palpable cords affecting two joints may be injected or one palpable cord affecting two joints in the same finger may be injected at two locations during a single treatment visit. If a patient has other cords with contractures, those cords are injected at another treatment visit approximately 4 weeks apart.

[Patient's name] was diagnosed with Dupuytren's contracture on [date]. The patient has [specify number of cord(s) and degree(s) of contracture for MP joint release and/or PIP joint release]. The contracture(s) [has/have] resulted in [detail impact on patient's range of motion, including specific impact on joints and fingers]. By treating [patient's name] with XIAFLEX®, I anticipate the following outcomes: [express the physician's professional opinion about the potential to reach the anticipated outcome]. [If appropriate, provide any past clinical experiences that the physician may have had with XIAFLEX®.]

I will be using the following codes to bill for the XIAFLEX® and procedures:
[Insert code(s)]

If you have any questions regarding the material that I have provided, please do not hesitate to contact me. Thank you in advance for your prompt attention to this matter.

Sincerely,

[Physician's name and credentials]
[Title]
[Name of practice]
[Street address]
[City, state, ZIP code]
[Phone number]

Enclosures: [Patient medical records/chart notes]
[XIAFLEX® (collagenase clostridium histolyticum) full Prescribing Information]

MM-05779/August 2022



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
Injection	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®) Commercial: Bill as 90 units Medicare: Bill as two separate lines <i>Line 1: J0775 (58 units[†])</i> <i>Line 2: J0775 (32 units[‡])</i> <i>and apply the JW modifier</i>
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 29130*: Application of finger splint; static	N/A

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

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

[‡]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.

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.

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 December 1, 2023.

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 December 1, 2023.

Correct coding for finger splint applications. Optum360® EncoderPro.com. <https://www.encoderpro.com/epro/logon.do>. Accessed December 1, 2023.

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 <i>Line 1: 1 unit</i> <i>Line 2: 1 unit and apply the most appropriate modifier</i>	J0775 (represents 0.01 mg of XIAFLEX®) Commercial: Bill as 180 units Medicare: Bill as two separate lines <i>Line 1: J0775 (116 units[†])</i> <i>Line 2: J0775 (64 units[‡])</i> <i>and apply the JW modifier</i>
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 <i>Line 1: 1 unit</i> <i>Line 2: 1 unit and apply the most appropriate modifier</i> 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 Endo Advantage™ (877-942-3539) or the payor’s Provider Service Representative to acquire more information on coding guidance.



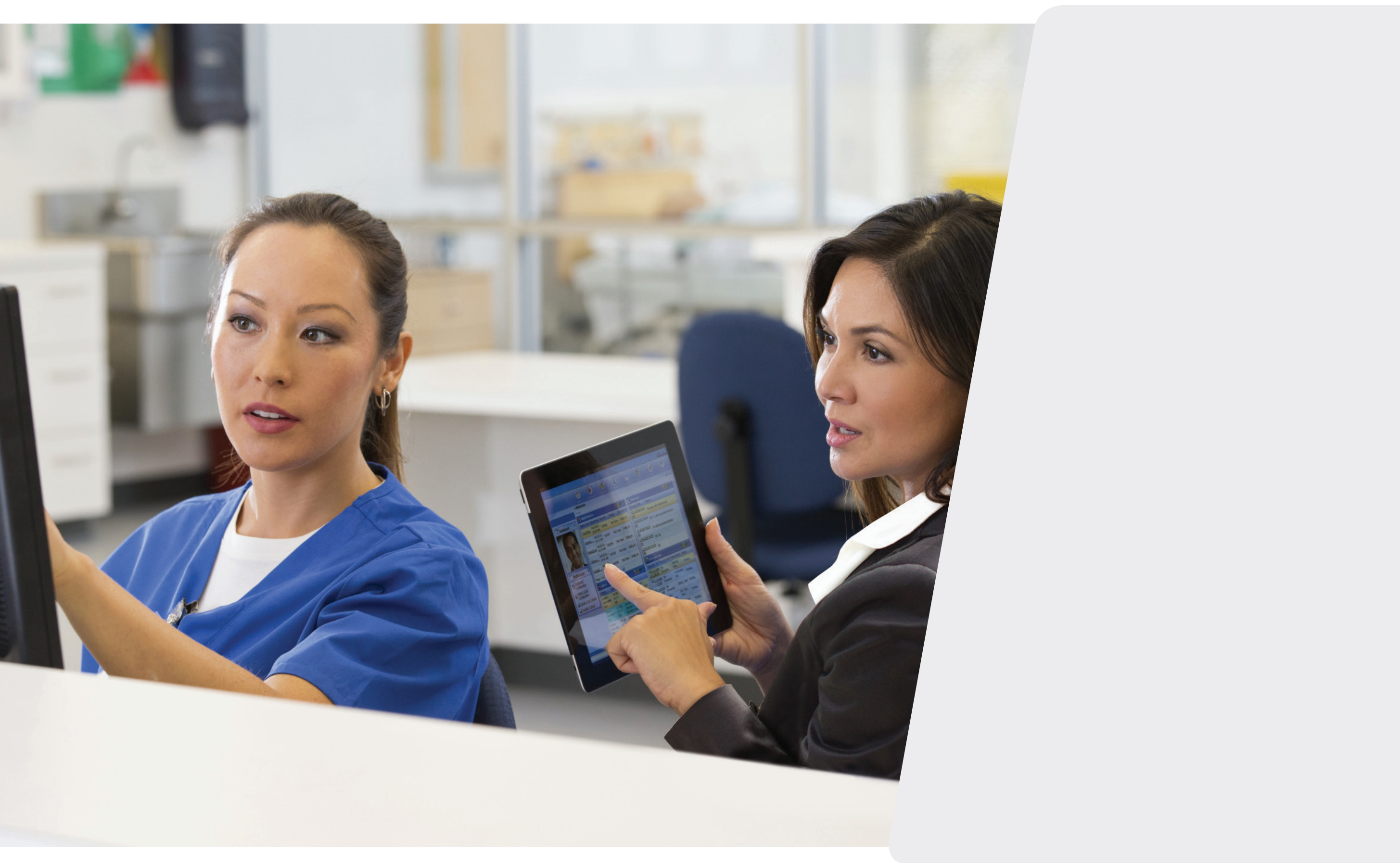
DEDICATED SUPPORT

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

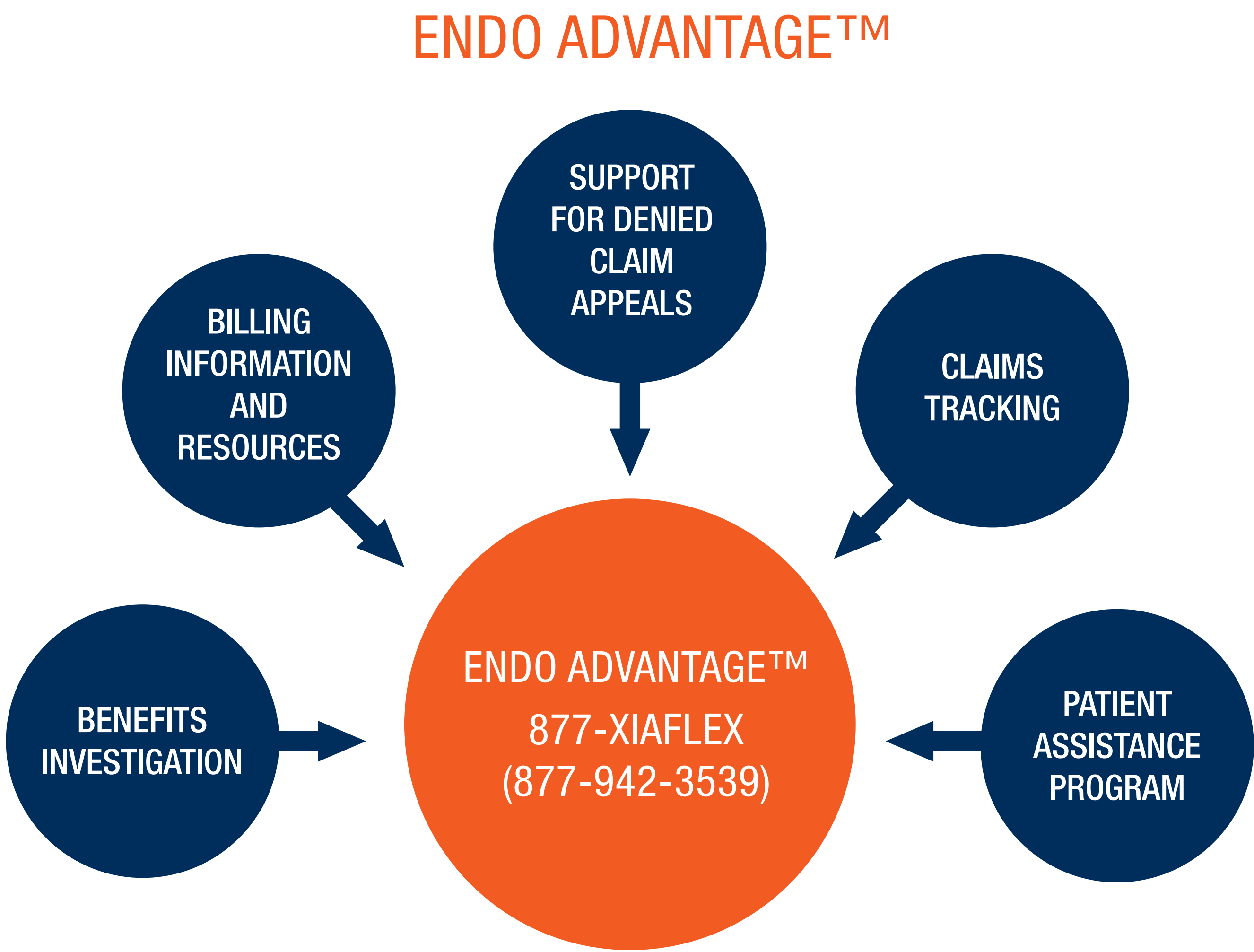


Please see [Indication and Important Safety Information](#).
Click for full [Prescribing Information](#) and [Medication Guide](#).

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.



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

Click for full [Prescribing Information](#) and [Medication Guide](#).

References: 1. XIAFLEX® [package insert]. Malvern, PA: Endo Pharmaceuticals Inc. 2. Data on File. DOF-XDC-46. Endo Pharmaceuticals Inc.; December 6, 2023.



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