XIAFLEX®
collagenase clostridium histolyticum

CHART DOCUMENTATION GUIDE

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

This document is provided to help educate Healthcare Professionals regarding assembling clinical information typically required by payors for the purposes of confirming coverage.

Diagnosis: _____

Type of contracture (check all that apply): ☐ MP ☐ PIP

Degree of contracture(s): _____

Affected finger(s) (check all that apply):
☐ R1 ☐ R2 ☐ R3 ☐ R4 ☐ L1 ☐ L2 ☐ L3 ☐ L4

Palpable cord(s): ☐

Prior treatments: _____

Injection Procedure Documentation

- ☐ Evaluate palpable cord(s), noting hand, finger(s), and joint(s) to be treated
- ☐ Reference outcome of table top test
- ☐ Explain protocol for injection to patient
- ☐ Provide patient with copy of XIAFLEX® Medication Guide and instruct patient to read it
- ☐ Inform patient about potential adverse reactions and what to do if one or more occurs, including pain, bruising and swelling at and around the injection site. Inform patient about serious adverse reactions
- ☐ If 2 joints on the same hand are to be treated during a single treatment visit, two vials of XIAFLEX® will need to be reconstituted
- ☐ Inject each cord with the appropriate volume of reconstituted XIAFLEX® in accordance with the Prescribing Information (Note the following: Injected 0.58 mg XIAFLEX® and discarded 0.32 mg). Up to 2 cords may be injected in the same hand during a treatment visit
- ☐ Wrap hand with bulky gauze dressing
- ☐ Instruct patient to keep hand elevated until bedtime and limit motion of the treated finger(s)
- ☐ Instruct the patient not to attempt to disrupt the injected cord(s) by self-manipulation and to return to the healthcare provider's office for follow-up and a finger extension procedure(s), if needed. Have patient schedule his/her finger extension procedure 24-72 hours after injection(s)
- ☐ Discard the unused portion of the reconstituted solution and diluent after injection. Do not store, pool, or use any vials containing unused reconstituted solution or diluent

Finger Extension Procedure Documentation

- ☐ Evaluate treated hand for a contracture that persists, noting any possible adverse reactions
- ☐ Administer local anesthesia, at your discretion, and note type and volume of anesthetic administered
- ☐ Perform extension procedure in accordance with the Prescribing Information up to 3 times per cord at 5- to 10-minute intervals, noting outcomes of each extension
- ☐ Assess residual contracture, if any
- ☐ Assess range of motion
- ☐ Address and document any adverse reactions that occur during extension procedure
- ☐ Fit patient with splint (and/or send to physical therapist for splinting) and provide instructions for use at bedtime for up to 4 months
- ☐ Counsel patient on at-home care. Instruct patient to perform finger extension and flexion exercises several times a day for several months
- ☐ Instruct patient to return to office for follow-up

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 MP or 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

Please see Important Safety Information continued on next page.

Please click here for full Prescribing Information, including Medication Guide.

IMPORTANT SAFETY INFORMATION FOR XIAFLEX® CONTINUED

- Other XIAFLEX®-associated serious local adverse reactions in the controlled and uncontrolled portions of the 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%). Cases of skin laceration requiring skin graft after finger extension procedures have been reported post-marketing. Signs or symptoms that may reflect serious injury to the injected finger/hand should be promptly evaluated because surgical intervention may be required
- 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 study 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

Please click here for full Prescribing Information, including Medication Guide.

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an endo international company

Rx Only

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