Enzyme Injection for Dupuytren's Contracture (XIAFLEX®) - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: March 15, 2024

Important Notices

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System
Guideline Name: Enzyme Injection for Dupuytren's Contracture (XIAFLEX®) (Single Service)

Literature review current through: 3/15/2024
Document last updated: 3/15/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

Non-Surgical Management

Service: Enzyme Injection for Dupuytren's Contracture (XIAFLEX®)

General Guidelines

- **Units, Frequency, & Duration:** Single-use glass vials of Xiaflex® (U.S. brand name) containing 0.9 mg of collagenase clostridium histolyticum as a sterile, lyophilized powder for reconstitution. Sterile diluent for reconstitution is also provided in a single-use glass vial.[1]
- **Criteria for Subsequent Requests:** Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.[1]
- **Recommended Clinical Approach:**
    - Collagenases are proteolytic enzymes that hydrolyze collagen, lysing the collagen helical fibers and disrupting the collagen cords.[2,3] Xiaflex is an injectable systemic collagenase enzyme that is FDA-approved to treat the following[1]:
        - Adults with Dupuytren contracture with a palpable cord, and contracture involving the metacarpophalangeal (MP) or proximal interphalangeal (PIP) joints
        - Treatment of adult men with Peyronie disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.
    - Injection of XIAFLEX into a Dupuytren's cord, which is comprised mostly of collagen, may enzymatically disrupt the cord.
    - About 24 hours after each injection, the hand is evaluated and manipulated in most cases to facilitate rupture of the cord (finger extension procedure).[1]
- **Exclusions:** This service is specific to Dupuytren's contractures (hand) only. It does not address using this medication in patients with Peyronie disease. This agent is not indicated for use in the foot.

Medical Necessity Criteria

Indications

➔ ***Enzyme injection for Dupuytren's contracture (XIAFLEX®)*** is considered appropriate if **ANY** of the following is **TRUE**:

◆ The patient is being considered for an initial therapy request, and **ALL** of the following criteria are met:

- The patient is 18 years of age or older; **AND**
- Documented diagnosis of Dupuytren's contracture with a palpable cord at the MP or PIP joint[4]; **AND**

- Documentation of a positive "tabletop test" (i.e., unable to place the affected finger(s) and palm flat against a tabletop simultaneously); **AND**
- Documentation that the flexion deformity results in functional limitations impacting the patient's activities of daily living (ADLs); **AND**
- The total number of injections does not exceed 1 injection per cord per 4-week period, and no more than 3 total injections in a 12-week period; **AND**
- No more than 2 injections in the same hand per session; **AND**
- If **ANY** of the following is **TRUE**[4]:
    - If isolated metacarpophalangeal (MP) joint involvement (per digit): documented contracture of at least 20 degrees flexion; ***OR***
    - If isolated proximal interphalangeal (PIP) joint involvement (per digit): documented contracture of at least 20 degrees flexion; **AND**
- If **ALL** of the following are **TRUE**:
    - The patient must be nicotine-free for six weeks prior to the anticipated procedure date; **AND**
    - Individuals who have been nicotine users prior to the anticipated procedure date must provide documentation of nicotine cessation, as evidenced by negative lab test report for nicotine and cotinine, to have been performed within two weeks of the planned procedure[5-7]; **OR**

◆ If the patient is being considered for a subsequent therapy request, and **ALL** of the following criteria are met:

- All of the Initial Treatment Criteria listed above are met; **AND**
- The patient has previously received Xiaflex; **AND**
- Documentation of positive clinical response (reduction in contraction to less than or equal to 5 degrees of flexion immediately following treatment) to prior treatment with Xiaflex; **AND**
- The previous treatment was at least 4 weeks ago; **AND**
- Metacarpophalangeal (MP) or proximal interphalangeal (PIP) contracture remains in the affected cord since the

previous injection, and the contracture is greater than 10 degrees.

Non-Indications

➔ ***Enzyme Injection for Dupuytren's Contracture (XIAFLEX®)*** is not considered appropriate if **ANY** of the following is **TRUE**:

- The total number of injections is greater than 3 injections per specific cord (finger) in a patient's lifetime; **OR**
- For a subsequent injection, the last injection was less than 4 weeks prior to this request; **OR**
- The patient has received surgical treatment (e.g., fasciectomy, fasciotomy) on the selected primary joint within 90 days of the first injection of this agent[5]; **OR**
- The patient has received anticoagulation medications (except for up to 150 mg of aspirin per day) within 7 days prior to the treatment date.[6]

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description/Definition
J0775	Injection, collagenase, clostridium histolyticum, 0.01 mg
20527	Injection, enzyme (eg, collagenase), palmar fascial cord (ie, Dupuytren's contracture)
26341	Manipulation, palmar fascial cord (ie, Dupuytren's cord), post enzyme injection (eg, collagenase), single cord

Medical Evidence

Lambi and colleagues (2023) examined pharmacotherapies in Dupuytren disease, with current and novel strategies. They discuss the use of collagenase therapy as currently the only approved nonsurgical treatment, other than local corticosteroid injections. Surgical treatment with limited fasciectomy and dermatofasciectomy are considered the gold standard for operative care due to their proven efficacy and low recurrence rates. Minimally invasive treatments other than collagenase and corticosteroid injections are being investigated as surgical alternatives in an effort to reduce high complication rates with surgical interventions. Nonsteroidal anti-inflammatory medications (NSAIDs), interferons, systemic colchicine, anti-oxidants, antihypertensive and vasoactive medications (ACE inhibitors and calcium channel blockers, antiestrogen and metformin are among a number of pharmacologic agents under investigation for use in Dupuytren disease.[2]

Sandler et al. (2022) performed a systematic review of the literature regarding treatment of Dupuytren's contracture with collagenase in metacarpophalangeal joints (MPCJs) and/or proximal interphalangeal joints (PIPJs) of the fingers. The evidence revealed that successful treatments reduced contractures to less than or equal to five degrees immediately, with minimal adverse effects related to treatment. It was found that initial contracture reduction was greater in MPCJs than in PIPJs. Recurrence was found in 23% of treated joints, within 6-24 months of treatment.[4]

Burge et al. (1997) completed a case-control study of 222 patients to examine the effects of smoking and alcohol on the risk of Dupuytren's contracture. It was found that current cigarette smoking was strongly associated with Dupuytren's contracture requiring surgical intervention. High incidence was found with alcohol use; however, the prevalence of the condition in alcoholics was likely attributed to the incidence of cigarette smoking in this population.[5]

References

1. US Food and Drug Administration (FDA). Highlights of prescribing information-Xiaflex. http://www.fda.gov. Updated August 2022.
2. Lambi, A. G., Popoff, S. N., Benhaim, P., & Barbe, M. F. (2023). Pharmacotherapies in Dupuytren disease: current and novel strategies. *J Hand Surg Am.* 2023;48(8): 810–821. https://doi.org/10.1016/j.jhsa.2023.02.003.
3. Calandruccio, JH. Dupuytren contracture. Campbell's Operative Orthopedics. 14th edition. 2021.
4. Sandler AB, Scanaliato JP, Dennis T, et al. Treatment of Dupuytren's contracture with collagenase: a systematic review. *Hand*. 2022;17(5):815-824. doi:10.1177/1558944720974119.
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6. Frey M. Risks and prevention of Dupuytren's contracture. *Lancet*. 1997;350(9091):1568. doi:10.1016/S0140-6736(05)64010-X.
7. An HS, Southworth SR, Thomas Jackson W, Russ B. Cigarette smoking and Dupuytren's contracture of the hand. *J Hand Surg Am*. 1988;13(6):872-874. doi:10.1016/0363-5023(88)90262-6.

Clinical Guideline Revision History/Information

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