



Collagenase (Xiaflex) Treatment

Origination: 07/15/11	Revised: 09/01/17	Annual Review: 11/07/19
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to *Collagenase (Xiaflex) Treatment* in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Compliance Status

- This procedure is in compliance with current Federal Drug Administration regulations.

Additional Information

- A new injectable Collagenase clostridium Histolyticum (Xiaflex) has been FDA approved for use in these conditions.

Definitions

- Dupuytren's disease is a benign fibroproliferative condition characterized by excessive collagen deposition causing abnormal thickening of the palmar fascia. This can result in the formation of nodules and a ropelike cord beneath the skin of the palm, stretching from the palm into the fingers. Gradually, the progression of these cords may cause the fingers to bend into the palm resulting in permanent joint contractures (referred to as Dupuytren's contracture).
- The cause of Dupuytren's contracture is unknown, but minor trauma and genetic predisposition may play a role. Men are more likely to be affected than women, and the symptoms of the disease are more severe in older men and in people of northern European descent. One or both hands may be affected, and the ring finger is most often affected, followed by the little, middle, and index fingers. The Metacarpal-Phalangeal Joint (MP joint), and the Proximal Inter-Phalangeal Joint (PIP joint) are the most affected joints of the fingers.
- Peyronie's disease is a connective tissue disorder that involves the growth of fibrous plaques in the penis that occurs in roughly 5% of men. This results in an abnormal curvature that can cause pain and/or erectile dysfunction.



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Coverage Guidelines for Dupuytren's contracture

- 1.0 The use of collagenase clostridium histolyticum is covered for the treatment of *Dupuytren's contracture* if ALL of the following criteria are met:
 - 1.1 A finger flexion contracture with a palpable cord is present of at least 20–100 degrees in a MP joint or 20–80 degrees in a PIP joint;
 - 1.2 A positive “Table Top” test is present (unable to simultaneously place palm and affected fingers flat against a table top);
 - 1.3 No surgical treatment on the affected finger was performed within 90 days of anticipated injection;
 - 1.4 Member has not received any anticoagulation medication within seven (7) days of anticipated injection;
 - 1.5 Injection is to be administered by a physician who is experienced in hand injections and can attest to completion of a training program sponsored by the manufacturer.
- 2.0 If the above criteria are met, only two (2) cords should be injected at a time.
- 3.0 Repeat injections up to three (3) times per cord at four (4) weeks may be performed.
- 4.0 Injections, follow-up visits, and splinting should be performed as per manufacturer's stated recommendations.
- 5.0 Warnings, cautions, and surveillance for possible side-effects should be observed by the prescribing physician as per manufacturer's stated recommendations.

Coverage Guidelines for Peyronie's disease

- 1.0 The use of collagenase clostridium histolyticum is covered for the treatment of *Peyronie's disease* if ALL of the following criteria are met:
 - 1.1 The Member is in the stable/chronic phase of Peyronie's disease;
 - 1.2 The Member has a palpable Peyronie's plaque;
 - 1.3 The Member has a documented penile curvature deformity of at least 30 degrees either by notes, photos, or goniometer measurements;



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- 1.4 The Member is 18 years old or greater;
- 1.5 The prescribing physician must be a Urologist certified through the Xiaflex REMS program.
- 2.0 If the above criteria are met, only one (1) plaque should be injected at a time.
- 3.0 Repeat injections up to three (3) times per plaque at four (4) weeks may be performed.
- 4.0 Injections, follow-up visits, and splinting should be performed as per manufacturer's stated recommendations.
- 5.0 Warnings, cautions, and surveillance for possible side-effects should be observed by the prescribing physician as per manufacturer's stated recommendations.

Exclusion Criterion

- All other indications or usage are considered to be experimental/investigational and are not considered a covered benefit.

References:

1. Hurst LC, et al. Injectable Collagenase clostridium Histolyticum for Dupuytren's Contracture (CORD I). N Engl J Med. 2009;361(10) 968-979.
2. Gilpin D, Coleman S, et al. Injectable Collagenase Clostridium Histolyticum (Cord II). J Hand Surg. 2010; 35(12) 2027-2038.
3. CMS. LCD for Collagenase clostridium histolyticum. Florida Region IV. 2010.
4. FDA. FDA approves Xiaflex for debilitating hand condition. Feb. 2010.
5. XIAFLEX® [Prescribing Information]. Malvern, PA; Auxilium Pharmaceuticals, Inc. January 2014.
6. Gelbard M. Goldstein I. Hellstrom WJ, et al. Clinical efficacy, safety and tolerability of collagenase clostridium histolyticum for the treatment of Peyronie disease. J Urol. 2013;190(1):199-207.



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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.