

*Dupuytren's Contracture Treatment Guidelines*

<b>Origination:</b> 07/15/11	<b>Revised:</b>	<b>Annual Review:</b> 12/15/11
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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 *Dupuytren's Contracture Treatment Guidelines* 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:

***Additional Information***

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

***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.

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### **Recommendation, continued:**

#### *Eligibility Criteria*

- The use of Collagenase clostridium Histolyticum is covered if ALL of the following criteria are met:
  - 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.
  - 2.) A positive “Table Top” test is present (unable to simultaneously place palm and affected fingers flat against a table top).
  - 3.) No surgical treatment on the affected finger was performed within 90 days of anticipated injection.
  - 4.) Member has not received any anticoagulation medication within seven (7) days of anticipated injection.
  - 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.
- If the above criteria are met, only one (1) cord should be injected at a time.
- Repeat injections up to three (3) times per cord at four (4) weeks may be performed.
- Injections, follow-up visits, and splinting should be performed as per manufacturer's stated recommendations.
- Warnings, Cautions, and surveillance for possible side-effects should be observed as per manufacturer's stated recommendations.

#### *Exclusions*

- 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 (L31243). Florida Region IV. 2010.
4. FDA. FDA approves Xiaflex for debilitating hand condition. Feb. 2010.
5. XIAFLEX® [Prescribing Information]. Malvern, PA; Auxilium Pharmaceuticals, Inc. February 2010.

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### **Disclaimer Information:**

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans 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 Health Plans 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.