

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Injectable Clostridial Collagenase for Fibroproliferative Disorders

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	2/7/2012	Policy Last Updated:	4/2/2013
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Collagenases are enzymes that digest native collagen and are being evaluated for treatment of fibroproliferative disorders such as Dupuytren's contracture and Peyronie's disease. Clostridial collagenase is a bacterial collagenase derived from *Clostridium histolyticum*. Treatment of Dupuytren's contracture consists of injection of collagenase into the cord followed by manipulation of the finger if contracture persists. Injection may be done up to 3 times at 4-week intervals.

Injection with clostridial collagenase is intended to provide a non-operative treatment option for fibroproliferative disorders. Fibrotic tissue disorders, characterized by excessive collagen deposits, can affect the musculoskeletal system causing pain and limitation of movement and reduction of joint range of motion. Dupuytren's disease and adhesive capsulitis are such musculoskeletal disorders; Peyronie's disease is another example.

The mechanisms that contribute to the pathology are poorly understood. In Dupuytren's disease, collagen deposition results in nodules and cords in the palm and fingers resulting in pitting of the overlying cutis and flexion contractures. The standard of care for Dupuytren's disease is surgery, most commonly open fasciectomy. Other surgical procedures are percutaneous fasciotomy and needle fasciotomy. Surgery is recommended in patients with functional impairment and metacarpophalangeal-joint contractures of 30 degrees or more. There is no effective pharmacotherapy.

Adhesive capsulitis or "frozen shoulder" is treated with physiotherapy and mobilization in combination with analgesics or nonsteroidal anti-inflammatory drugs. Corticosteroid injection is used with caution. The prevalence of Dupuytren's disease and adhesive capsulitis is estimated at 3-6% and 2-3%, respectively, in the general population and increases with advancing age. Both conditions are more common in patients with diabetes or thyroid disease. Dupuytren's disease is more common in men and adhesive capsulitis more common in women.

Peyronie's disease is the development of abnormal scar tissue, or plaques, in the tunica albuginea layer of the penis causing distortion, curvature, and pain usually during erection. It occurs in 3-9% of men, most commonly between the ages of 45 and 60. In some cases, plaque does not cause severe pain or curvature, and the condition resolves on its own. In severe cases, erectile dysfunction can occur. The goal of treatment is to reduce pain and maintain sexual function. Treatments in early stages (before calcification) include vitamin E or para-aminobenzoate tablets (e.g., Potaba) although studies of oral therapies demonstrate inconsistent benefit. Intralesional injection therapy consisting of injection of interferon-alpha-2b or calcium channel-blockers (e.g., verapamil) is the current standard of therapy. (2) Surgical procedures involve the excision (removal) of hardened tissue and skin graft, the removal or

pinching (plication) of tissue opposite the plaque to reduce curvature (called the Nesbit procedure), a penile implant, or a combination of these.

For patients with Dupuytren's contracture, the evidence from clinical trials suggests that injectable clostridial collagenase provides short-term release of contracture. Therefore, injectable clostridial collagenase may be considered medically necessary as an alternative to surgical options.

For other disorders, there is less evidence. Small trials demonstrated short-term improvement in patients with Peyronie's disease. Larger trials directly comparing outcomes with current treatment options are required. Therefore, based on available evidence and clinical input, injection of this agent is considered not medically necessary for all other treatment indications, including Peyronie's disease and adhesive capsulitis.

Medical Criteria:

Injectable clostridial collagenase is covered for all members who meet all of the following criteria:

- adult patients with Dupuytren's contracture with
- a palpable cord, and
- functional impairment, and
- fixed-flexion contractures of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more excluding the thumb.

Policy:

Prior authorization is required for BlueCHiP for Medicare and recommended for all other BCBSRI products.

Injectable clostridial collagenase is considered medically necessary, for up to three injections at intervals of at least thirty-days, when the above criteria is met

Injectable clostridial collagenase is considered not medically necessary for all other indications due to the lack of peer-reviewed medical literature which supports use.

Coverage:

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable "Services Not Medically Necessary" benefit.

Coding:

The following codes require preauthorization for BlueCHiP for Medicare and recommended for all other BCBSRI products:

20527, J0775

The manipulation of the cord is only covered if the injection is covered:

26341

It is considered incorrect coding to report the injection with the following CPT code:

20550

Unlisted code:

After 1/1/2012, 20527 should be used in place of the unlisted code 26989.

Also Known As:

Xiaflex™

Published:

Provider Update, June 2013
Provider Update, October 2012
Provider Update, April 2011
Provider Update, July 2010

References:

- I. Hurst LC BM, Wang ED. Injectable clostridial collagenase: striving toward non-operative treatment options for fibroproliferative disorders. American Academy of Orthopaedic Surgeons. 2009. Available online at: http://www.aaos.org/research/committee/research/Kappa/KD2009_Hurst.pdf. Last accessed February 2013
- II. Witthaut J, Bushmakina AG, Gerber RA et al. Determining clinically important changes in range of motion in patients with Dupuytren's Contracture: secondary analysis of the randomized, double-blind, placebo-controlled CORD I study. Clin Drug Investig 2011; 31(11):791-8
- III. Hurst LC, Badalamente MA, Hentz VR et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med 2009; 361(10):968-79
- IV. Chen NC SR, Shauver MJ et al. A systematic review of outcomes of fasciotomy, aponeurotomy, and collagenase treatments for Dupuytren's contracture. Hand 2011; 2011(September 28):6(3):250-5
- V. Badalamente MA, Hurst LC. Efficacy and safety of injectable mixed collagenase subtypes in the treatment of Dupuytren's contracture. J Hand Surg Am 2007; 32(6):767-74.

History:

4/2/13 Annual Review
2/27/12 Annual Review
2/7/12 Coverage Change
2011 New Policy

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