

Corporate Medical Policy

Injectable Clostridial Collagenase for Fibroproliferative Disorders

File Name: injectable_clostridial_collagenase_for_fibroproliferative_disorders
Origination: 6/2010
Last CAP Review: 2/2011
Next CAP Review: 2/2012
Last Review: 12/2011

Description of Procedure or Service

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. Injections 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 metacarpo-phalangeal (MP) 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 non-steroidal 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.

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), penile implant, or a combination of these.

Regulatory Status

Injectable Clostridial Collagenase for Fibroproliferative Disorders

In February 2010, the FDA approved Auxilium Pharmaceutical Inc.'s biologics license application for clostridial collagenase histolyticum (Xiaflex™) for treatment of adult patients with Dupuytren's contracture with a palpable cord. The FDA labeling for Xiaflex™ states that up to 3 injections at 4-week intervals may be given into a palpable Dupuytren's cord with a contracture of a metacarpo-phalangeal (MP) joint or a proximal interphalangeal (PIP) joint

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Injectable clostridial collagenase for the treatment of Dupuytren's contracture in adult patients with a palpable cord may be considered medically necessary, for up to three injections at intervals of at least thirty-days.

Injectable clostridial collagenase is considered investigational for all other indications including, but not limited to, Peyronie's disease, and adhesive capsulitis.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Injectable Clostridial Collagenase is covered

Injectable clostridial collagenase for the treatment of Dupuytren's contracture in adult patients with a palpable cord may be considered medically necessary, for up to three injections at intervals of at least thirty-days.

When Injectable Clostridial Collagenase is not covered

Injectable clostridial collagenase is considered investigational for all other clinical indications, including, but not limited to Peyronie's disease and adhesive capsulitis. BCBSNC does not cover investigational services.

Policy Guidelines

The evidence from clinical trials suggests that injectable clostridial collagenase provides short-term release of contracture in Dupuytren's disease. While evidence of long-term recurrence rates is limited, this may be an appropriate treatment option in adult patients with a palpable cord based on short-term evidence of effectiveness and a preponderance of agreement from clinical input. Therefore, injectable clostridial collagenase may be considered medically necessary as an alternative to surgical options. A comparison of overall outcomes compared to surgical intervention may also be useful; however, studies with direct comparisons are not available. Potentially serious adverse events also warrant further investigation. 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 investigational for all other treatment indications, including Peyronie's disease and adhesive capsulitis.

Billing/Coding/Physician Documentation Information

Injectable Clostridial Collagenase for Fibroproliferative Disorders

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 20550, 20527, 26341, 26989, J0775

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.19, 3/11/10.

Food and Drug Administration (FDA). BLA Approval for Xiaflex, clostridial collagenase histolyticum, Auxilium Pharmaceuticals, Inc. Retrieved on May 6, 2010 from http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/125338s000ltr.pdf

Hurst Lawrence C, Badalamente Marie A, Wang. (2009). Injectable Clostridial Collagenase: Striving Toward Non-Operative Treatment Options For Fibroproliferative Disorders. Retrieved on May 6, 2010 from http://www.aaos.org/research/committee/research/Kappa/KD2009_Hurst.pdf

Senior Medical Director review 5/17/2010

Specialty Matched Consultant Advisory Panel review 7/2010

Food and Drug Administration (FDA). Warning Letter and Notice of Violation. June 10, 2010. Retrieved on January 21, 2011 from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivities/yFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM215799.pdf>

Specialty Matched Consultant Advisory Panel review 2/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.19, 3/10/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.19, 11/10/11

Medical Director review 12/2011

Policy Implementation/Update Information

06/08/10 Implementation of new policy titled "Injectable Clostridial Collagenase for Fibroproliferative Disorders". Injectable clostridial collagenase is considered investigational for all indications including, but not limited to, Dupuytren's contracture, Peyronie's disease, and adhesive capsulitis. Added CPT code C9266. (mco)

8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. No change in policy statement. (mco)

10/12/10 Added codes J3490 and J9999 to Billing/Coding section (mco)

1/4/11 Codes J3490, J3590, J9999 and C9266 deleted from policy. New code specific to injection of

Injectable Clostridial Collagenase for Fibroproliferative Disorders

- Clostridial Collagenase (Xiaflex) added to Billing/Coding section: **J0775**. (mco)
- 3/15/11 Specialty Matched Consultant Advisory Panel review 2/2011. References updated. (mco)
- 5/24/11 References updated. No changes to policy statements. (mco)
- 12/30/11 Policy Statements revised as follows: “Injectable clostridial collagenase for the treatment of Dupuytren’s contracture in adult patients with a palpable cord may be considered medically necessary, for up to three injections at intervals of at least thirty-days. Injectable clostridial collagenase is considered investigational for all other indications including, but not limited to, Peyronie’s disease, and adhesive capsulitis.” “When Covered” and “When not Covered” sections revised to reflect coverage criteria. CPT codes 20527 and 26341 added to “Billing/Coding” section and are effective 1/1/2012. CPT code 26989 deleted. “Policy Guidelines” section updated. References updated. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.