Injectable Clostridial Collagenase for Fibroproliferative Disorders

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 fasciectomy and needle fasciectomy. 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.

The evidence from one large clinical trial suggests that injectable clostridial collagenase provides short-term release of contracture in Dupuytren’s disease. However, longer term recurrence rates are not reported. A comparison of overall outcomes compared to surgical intervention may also be useful. 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.

Medical Criteria:

Prior authorization is required.

Injectable clostridial collagenase is covered for BlueCHiP for Medicare members who meet 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.

All other uses are considered not medically necessary.

Policy:

Injectable clostridial collagenase is covered for BlueCHiP for Medicare members who met the medical criteria above. All other uses are considered not medically necessary.

For all other members, injectable clostridial collagenase is considered not medically necessary for all indications including, but not limited to, Dupuytren’s contracture,
Peyronie’s disease, and adhesive capsulitis due to the lack of peer-reviewed medical literature which supports use.

NOTE:
Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates scientific evidence with local expert opinion, and consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations, and the US Congress. BCBSRI policy is based upon peer-reviewed, scientifically controlled studies in the literature which demonstrate the superior health outcome of a service or treatment. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. BCBSRI and Medicare policies may differ; however, our BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers. (In some, but not all instances, BCBSRI offers more benefits than does Medicare).

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, Benefit Booklet, or Rite Care Contract for not medically necessary service benefit/coverage.

Coding:

The injection of clostridial collagenase should be reported with the unlisted CPT code: 26989

The supply of the clostridial collagenase should be reported with the HCPCS code: J0775 Injection, collagenase, clostridium histolyticum, 0.01 mg

It is considered incorrect coding to report the injection with the following CPT code: 20550

Also Known As:
Xiaflex™

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