Public Statement:

1. Dupuytren’s disease, a progressive fibro-proliferative disorder, is characterized by nodule formation and contracture of the palmar fascia, and may result in flexion deformity of the fingers and loss of hand function. The disease is common in men older than 40 years; and in persons who smoke, use alcohol, or have diabetes mellitus.

2. The symptoms of Dupuytren's contracture are often mild and painless and do not require treatment. In some patients, however, it may progress to the next stage, in which cords of fibrous tissue form in the palm and run into the fingers or thumb, eventually, pulling them into a permanently flexed position, making it difficult to perform activities of daily living.

3. Several treatments are available to treat Dupuytren’s contracture and are generally covered when used for this condition.

Medical Policy Statement:

1. Collagenase clostridium histolyticum (Xiaflex) injections are considered medically necessary for the treatment of adults with Dupuytren's contracture with a palpable cord.

2. Percutaneous needle aponeurotomy is considered medically necessary for the treatment of adults with Dupuytren's contracture with a palpable cord.

3. Ortho-voltage radiation is considered medically necessary for the treatment of early-stage Dupuytren's contracture stage N, N/I. (Note: stage N: nodules/cords, no extension deficit/ flexion deformity; stage N/I: less than or equal to 10 degrees deficit).

Limits:
Collagenase clostridium histolyticum injections are considered experimental and investigational for all other indications (e.g., Peyronie's disease).

**Background:**

Dupuytren’s contracture initially can be managed with observation and non-surgical therapy. It will regress without treatment in about 10% of patients. Injection of steroids into the nodule has been shown to reduce the need for surgery. Surgical referral should be made when metacarpophalangeal (MCP) joint contracture reaches 30 degrees or when proximal interphalangeal (PIP) joint contracture occurs at any degree. In-office percutaneous needle aponeurotomy is an alternative to surgery (Trojian and Chu, 2007).

Swartz and Lalonde (2008) stated that treatment of Dupuytren's disease is offered to symptomatic patients with painful nodular or disabling contracture. Limited fasciectomy of the involved abnormal structures followed by hand therapy is standard treatment, but it is associated with serious potential complications. Moreover, recurrence is common. New treatments include the injection of clostridial collagenase, which works by breaking down the excessive build-up of collagen in the hand.

In a phase II open-label clinical trial, Badalamente and Hurst (2000) examined the clinical safety and effectiveness of clostridial collagenase injection as a non-surgical treatment of Dupuytren's disease. A total of 35 patients entered the study (3 women and 32 men). The mean age was 65 years. The first 6 patients were treated following a dose escalation protocol and received 300, 600, 1200, 2400, 4800, and 9600 units (U) collagenase injected into the cord that was causing contracture of the MCP joint. There were no beneficial clinical effects of these injections. The remaining 29 patients had collagenase injections at a dose level of 10,000 U into cords that are causing contractures of 34 MCP joints, 9 PIP joints, and 1 thumb. Twenty-eight of the 34 MCP joint contractures corrected to normal extension (0 degrees) and 2 of the 34 MCP joint contractures corrected to 5 degrees of normal extension, with full range of motion, within 1 to 14 days of injection. In patients with PIP joint contractures, 4 of the 9 joints corrected to normal (0 degrees). One PIP joint corrected to within 10 degrees of normal and 2 corrected to within 15 degrees of normal. There were 2 failures; these patients required surgery. The mean follow-up period was 20.0 +/- 5.6 months for the MCP joints and 14.1 +/- 6.6 months for the PIP joints. Clostridial collagenase injection of Dupuytren's cords causing MCP and PIP joint contractures appears to have merit as non-surgical treatment of this disorder. The authors stated that pending further placebo, double-blind studies, collagenase injection to treat Dupuytren's disease may be a safe and effective alternative to surgical fasciectomy.

Badalamente et al (2002) reported that in a series of controlled phase II clinical trials, excessive collagen deposition in Dupuytren's disease has been targeted by a unique non-operative method using clostridial collagenase injection therapy to lyse and rupture finger cords causing MCP and/or PIP joint contractures. A total of 49 patients were
treated in a random, placebo-controlled trial of one dose of collagenase versus placebo at 1 center. Subsequently 80 patients were treated in a random, placebo-controlled, dose-response study of collagenase at 2 test centers. The results of these studies indicated that non-operative collagenase injection therapy for Dupuytren's disease is both a safe and effective method of treating this disorder in the majority of patients as an alternative to surgical fasciectomy.

In a prospective, randomized, double-blind, placebo-controlled, multi-center study, Hurst et al (2009) examined the effects of injectable collagenase clostridium histolyticum for the treatment of Dupuytren's contracture. These investigators enrolled 308 patients with joint contractures of 20 degrees or more. The primary MCP or PIP joints of these patients were randomly assigned to receive up to 3 injections of collagenase clostridium histolyticum (at a dose of 0.58 mg per injection) or placebo in the contracted collagen cord at 30-day intervals. One day after injection, the joints were manipulated. The primary end point was a reduction in contracture to 0 to 5 degrees of full extension 30 days after the last injection. Twenty-six secondary end points were evaluated, and data on adverse events were collected. Collagenase treatment significantly improved outcomes. More cords that were injected with collagenase than cords injected with placebo met the primary end point (64.0 % versus 6.8 %, p < 0.001), as well as all secondary end points (p < or = 0.002). Overall, the range of motion in the joints was significantly improved after injection with collagenase as compared with placebo (from 43.9 to 80.7 degrees versus from 45.3 to 49.5 degrees, p < 0.001). The most commonly reported adverse events were localized swelling, pain, bruising, pruritus, and transient regional lymph-node enlargement and tenderness. Three treatment-related serious adverse events were reported: 2 tendon ruptures and 1 case of complex regional pain syndrome. No significant changes in flexion or grip strength, no systemic allergic reactions, and no nerve injuries were observed. The authors concluded that collagenase clostridium histolyticum injection significantly reduced contractures and improved the range of motion in joints affected by advanced Dupuytren's disease.

References:


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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