

Medical Coverage Policy | Xiaflex (Clostridial Collagenase)



EFFECTIVE DATE: 06|01|2018

POLICY LAST UPDATED: 08|07|2018

OVERVIEW

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. Injection with clostridial collagenase is intended to provide a non-operative treatment option for fibroproliferative disorders.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

BlueCHiP for Medicare

Xiaflex will be approved when ALL of the following are met:

1. The patient has ONE of the following:
 - a. There is documentation that the patient is currently being treated with the requested agent
OR
 - b. Dupuytren's contracture with palpable cord AND BOTH of the following:
 - i. Contracture measures 20 degrees or more at either the metacarpophalangeal (MP) joint or the proximal interphalangeal (PIP) joint (excluding the thumb)
AND
 - ii. The patient has functional impairment in the hand due to the contracture
OR
 - c. Peyronie's disease with palpable plaque AND ALL of the following:
 - i. The patient has stable Peyronie's disease
AND
 - ii. The patient has a curvature deformity of at least 30 degrees, documented with a vasoactive challenge, prior to treatment with the requested agent
AND
 - iii. The patient has intact erectile function (with or without use of medications)
AND
 - iv. The patient has sexual functional impairment
AND
2. The patient doesn't have any FDA labeled contraindications to therapy to requested agent
AND
3. The dose is within the FDA labeled dose

Length of Approval: 3 months for Dupuytren's Contracture
6 months for Peyronie's Disease

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare

POLICY STATEMENT

BlueCHiP for Medicare

Injectable clostridial collagenase is medically necessary when the medical criteria are met.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage for applicable physician administered drug benefits/coverage.

BACKGROUND

Dupuytren's Contracture

Dupuytren disease is a slowly progressing fibrosing disorder with thickening and shortening of the palmar fascia resulting in debilitating digital contracture. Typically the fourth and fifth digits (ring and pinkie fingers) are affected. This disease belongs to a group of fibromatoses including penile fibromatosis (Peyronie disease) as well as other conditions. Approximately half (45%) of affected patients have bilateral disease. The cause is unknown but family history is often found with males 3 times more likely to develop the disease and have higher disease severity. Risk factors include manual labor with vibration exposure, prior hand trauma, alcoholism, smoking, diabetes mellitus, hyperlipidemia, Peyronie disease and complex regional pain syndrome. Rheumatoid arthritis seems to be protective against development of Dupuytren disease.

Standard diagnostic laboratory or radiographic evaluations that apply to Dupuytren's are not available. Ultrasound can show the thickening of the palmar fascia and may be useful prior to intralesional injections. Observation is appropriate for patients with non-progressing, painless disease with minimal contractor and no functional impairment. These patients can be monitored every 6 to 12 months. Radiotherapy and corticosteroid injections have some evidence of efficacy but neither intervention is thought to reduce the rate of surgical intervention. Surgical intervention timing varies, but is usually performed when the MCP joint contracture exceeds 40 degrees or when the PIP joint contracture exceeds 20 degrees. Xiaflex pivotal trials required finger flexion contracture with palpable cord with at least 20% in either the MP or PIP joint. Postsurgical care consists of wound care, massage, passive stretching, active range of motion exercises, and splinting.

Peyronie's Disease

Peyronie's disease (PD) is defined by the American Urological Association (AUA) as an acquired penile abnormality characterized by fibrosis of the tunica albuginea, which may be accompanied by pain, deformity, erectile dysfunction, and/or distress. The prevalence rates vary on methodology employed, sample, PD definition and how men are queried. However, one population-based U.S. study (2011- including those 18 years of age and older) reported a prevalence rate of 0.5% for men who had been formally diagnosed, 0.8% for men diagnosed or treated for PD, and 13.1% for men diagnosed, treated, or had any symptom of PD. PD is characterized by excessive deposition of collagen forming a plaque within the penile tunica albuginea. Angulation can occur from the collagen deposition. It may continue to progress and can approach a maximum of a 90 degree angle. However, plaque resolution without treatment was found to occur in 12%-13% of patients.

Treatment is recommended when there is a significant impact on sexual function and/or is the source of patient or partner distress. Optimal therapy has not been determined. Observation is recommended in some patients whose pain/curvature are minimal and do not preclude normal sexual function. A placebo effect may be applicable in this patient population as some symptoms can improve without therapy in a significant number of men. The AUA guidelines (2015) recommend that oral NSAIDs be utilized for pain associated with PD. Additionally, the AUA states that intralesional collagenase with clinician/patient modeling is recommended when the patient has stable PD, a curvature >30 and <90 degrees, and when the patient has intact erectile function (regardless of whether medications are needed to obtain erection or not). Currently, collagenase is the only pharmacological treatment FDA approved for the treatment of Peyronie's Disease.

CODING

BlueCHiP for Medicare

The following code is covered when the medical criteria are met:

J0775 Injection, collagenase, clostridium histolyticum, 0.01 mg

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, October 2018

Provider Update, June 2018

Provider Update, January 2018

Provider Update, January 2017

Provider Update, January 2016

Provider Update, January 2015

Provider Update, June 2013

Provider Update, October 2012

Provider Update, April 2011

REFERENCES

1. Xiaflex (collagenase clostridium histolyticum) product information. Endo Pharmaceuticals, Inc. August 2017.

2. Dupuytren's contracture. Medscape. Available at: <http://emedicine.medscape.com/article/329414-overview>. Accessed 2/01/17.

3. Peyronie's Disease. Medscape. Available at: <http://emedicine.medscape.com/article/456574-treatment>. Accessed 2/1/17.

4. American Urological Association (AUA) Guideline. Peyronie's Disease. 2015. <https://www.auanet.org/common/pdf/education/clinical-guidance/Peyronies-Disease.pdf>. Accessed 2/01/2017.

5. Trojan, T and Stephanie Chu. Dupuytren's Disease: Diagnosis and Treatment. Am Fam Physician. 2007. Jul 1;76(1):86-89.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

