Xiaflex (collagenase clostridium histolyticum)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Xiaflex (collagenase clostridium histolyticum) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Xiaflex is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.
2. Xiaflex is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A.) Dupuytren's contracture: Chart notes or medical record indicating the affected joint, contracture, and a positive table top test (for new starts and continuation) and the number of injections the member has received (for continuation only).

B.) Peyronie's disease: Chart notes or medical record indicating palpable plaque, curvature, intact erectile function (for new starts and continuation) and the number of injections the member has received (for continuation only).

Criteria for Initial Approval

A. Dupuytren's contracture

Authorization of 6 months may be granted for the treatment of Dupuytren's contracture when all of the following criteria are met:

1. The member has a finger flexion contracture with a palpable cord in a metacarpophalangeal joint or a proximal interphalangeal joint prior to initiating Xiaflex therapy.
2. The contracture is at least 20 degrees prior to initiating Xiaflex therapy.
3. The member had a positive table top test, defined as the inability to simultaneously place the affected finger(s) and palm flat against a table prior to initiating Xiaflex therapy.
4. The member will receive a maximum of 3 injections per cord (4 weeks apart) as part of the current treatment.

B. Peyronie's disease

Authorization of 12 months may be granted for the treatment of Peyronie's disease when the following criteria are met:

1. The member has stable Peyronie's disease without clinical changes (e.g., worsening curvature) for at least three months.
2. The member has a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees prior to initiating Xiaflex therapy.
3. The member has intact erectile function (with or without medication).
4. The member is 18 years of age or older.
5. The member will receive a maximum of one treatment course with a maximum of 8 injections total, including any injections the patient has received for any previous treatment.

Continuation of Therapy

A. Dupuytren's contracture

Authorization of 6 months may be granted for the continuation of treatment for Dupuytren's contracture when all of the following criteria are met:

1. The patient meets all initial authorization criteria.
2. The member is continuing with a treatment course for the same cord. For treatment of a new cord or a previously-treated cord following recurrence, member must meet all initial authorization criteria.
3. The member has received less than 3 injections total per cord (4 weeks apart).

B. Peyronie's disease

Authorization of 12 months may be granted for the continuation of treatment for Peyronie's disease when all of the following criteria are met:

1. The member meets all initial authorization criteria.
2. The member has curvature deformity of at least 15 degrees at the time of the continuation request.
3. The member has received less than 8 injections total, including any injections the patient has received for any previous treatment.

Xiaflex is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0775 - Injection, collagenase, clostridium histolyticum, 0.01 mg

REFERENCES

- Xiaflex [package insert]. Endo Pharmaceuticals Inc.; June 2018.
- Hurst LC, Badalamente MA, Hentz VR, et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med. 2009;361(10):968-979.
- Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. *J Urol.* 2015;194(3):745-753.

POLICY HISTORY

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