Collagenase (Xiaflex®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Xiaflex is indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord.
B. 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.

All other indications are considered experimental/investigational and not medically necessary.

II. 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 tabletop 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).

III. PRESCRIBER SPECIALTIES

A. Dupuytren's contracture: The medication must administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture.
B. Peyronie's disease: The medication must be administered by a healthcare provider experienced in the treatment of urological disease and who has completed the Xiaflex REMS program requirements.

IV. EXCLUSIONS

Coverage will not be provided for cosmetic use (e.g., cellulite reduction treatment).

V. 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 tabletop 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 is 18 years of age or older.
5. The member will receive up to 3 injections maximum 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.

VI. 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 member 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.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Xiaflex (Collagenase Clostridium Histolyticum)	Dupuytren's Contracture	Route of Administration: Injection ≥18 Years 0.58mg per injection for up to 2 injections per hand. May administer up to 3 times per cord at approximately 4-week intervals

Xiaflex (Collagenase Clostridium Histolyticum)	Peyronie's Disease	Route of Administration: Injection ≥18 Years 0.58mg for each plaque formation once on each of 2 days, given 1 to 3 days apart, every 6 weeks x 4 cycles (Max of 8 injections)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Xiaflex [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2022.
2. 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.
3. Nehra A, Alterowitz R, Culkin DJ, et al. Peyronie's Disease: AUA Guideline. *J Urol.* 2015;194(3):745-753.

EFFECTIVE DATE

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