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P&T Date: 08/13/2026

Xiaflex® (collagenase clostridium histolyticum)

HCPCS: J0775

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved age
 - b. Diagnosis of Dupuytren's contracture:
 - i. A finger flexion contracture with a palpable cord of at least one finger (other than the thumb) involving the metacarpophalangeal (MP) joint or the proximal interphalangeal (PIP) joint
 - ii. Administering physician must be a surgeon who has experience and training in hand surgeries
 - c. Diagnosis of Peyronie's disease:
 - i. Prescribed by or in consultation with a urologist
 - ii. Palpable plaque and curvature deformity of 30° or greater at start of therapy
 - iii. Treatment with intralesional verapamil was ineffective, contraindicated, or not tolerated OR the patient has any of the following:
 - 1. The plaque has calcified
 - 2. There is a curvature of greater than 60°
 - 3. The plaque has been present for greater than 12 months
 - 4. The plaque is stable and has not changed over the last 6 months
 - d. Facility must be enrolled to receive Xiaflex through Xiaflex REMS™
 - e. Collagenase clostridium histolyticum will not be covered for cellulite or other cosmetic indications
 - f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: 3 months
 - c. Renewal Criteria: Not applicable as no further authorization will be provided

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Xiaflex is approved for the treatment of adult patients with Dupuytren's contracture (DC) with a palpable cord and the treatment of adult men with Peyronie's disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.
- Safety and efficacy of Xiaflex in Dupuytren's contracture was evaluated in two randomized, double-blind, placebo-controlled, multi-centered trials in 374 adult patients with Dupuytren's contracture. At study entry, patients must have had a finger flexion contracture with a palpable cord of at least one finger (other than the thumb) of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint and a positive "table top test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top. The cord affecting the selected primary joint received up to 3 injections of 0.58 mg of Xiaflex or placebo on days 0, 30, and 60. About 24 hours after each injection of study medication, if needed, the investigator manipulated the treated finger in an attempt to facilitate rupture of the cord. The primary endpoint was the proportion of patients who achieved a reduction in contracture of the selected primary joint (MP or PIP) to within 0° to 5° of normal 30 days after the last injection. Both studies showed statistically significant reduction in contracture in the Xiaflex group compared to the placebo group.
- The 2015 American Urological Association guidelines for the treatment of Peyronie's disease recommend the use of Xiaflex or intralesional verapamil for the treatment of PD with the caveat that Xiaflex should only be offered if the disease is stable. In clinical practice, stable disease is considered when the plaque has been present for greater than 12 months or the plaque has remained unchanged for over 6 months.
- Efficacy of interlesion verapamil has been studied in a randomized, parallel-group study of 53 patients with Peyronie's disease. Patients with calcified plaques, penile curvature more than 60 degrees, history suggestive of fracture penis, and any history of calcium channel blocker therapy or therapy interfering with calcium channel blocker were excluded. There was a significant improvement in patient satisfaction, curvature of penis, erectile function, and reduction in plaque size in patients who received verapamil. Pain decreased in both the groups considerably (97% and 91%, in verapamil and control groups, respectively) and overall satisfaction was higher in verapamil group (82%) than control group (40%).
- The efficacy of Xiaflex was evaluated in two randomized, double-blind, placebo-controlled, multi-centered trials in 832 adult males with Peyronie's disease. At study entry, patients must have had penile curvature deformity of at least 30 degrees in the stable phase of Peyronie's disease. Patients were excluded if they had a ventral curvature deformity, an isolated hourglass deformity, or a calcified plaque that could have interfered with the injection technique. At baseline, penile pain was either not present or was mild in most patients. Patients were given up to 4 treatment cycles of Xiaflex or placebo. In each treatment cycle, two injections of Xiaflex or two injections of placebo were administered 1 to 3 days apart. The primary endpoints were the percent change from baseline to week 52 in penile curvature deformity and the change from baseline to week 52 in the Bother domain score. The Bother domain score is a composite of the following patient-reported items: concern about erection pain, erection appearance, and the impact of Peyronie's disease on intercourse and on frequency of intercourse. Xiaflex treatment significantly improved penile curvature deformity in patients with Peyronie's disease compared with placebo. Xiaflex also significantly reduced patient-reported bother associated with Peyronie's disease compared with placebo.

- There are no head to head studies of Xiaflex and verapamil showing superiority of one over the other.
- Collagenase clostridium histolyticum also is approved for the treatment of moderate to severe cellulite in the buttock. This is considered a cosmetic use and therefore not covered under the medical benefit.

References:

1. Xiaflex [prescribing information]. Malvern, PA: Auxilium Pharmaceuticals, LLC; March 2026.
2. Shirazi M, Haghpanah AR, Badiie M, et al. Effect of intralesional verapamil for treatment of Peyronie's disease: a randomized single-blind, placebo-controlled study. *Int Urol Nephro*. 2009; 41 (3): 467 – 71.
3. Arya MC, Swami JP, Yogendra, et al. Intralesional verapamil for the treatment of peyronie's disease: a prospective study. *Int J Med Res Prof*. 2019; 5 (3): 152 - 155.
4. Nehra A, Alterowitz R, Culkin DJ, et al. American urological association (AUA) guideline: peyronie's disease. 2015. Available at: <https://www.auanet.org/guidelines/peyronies-disease-guideline#x2966>. Accessed on June 20, 2023.
5. Levine L, Rybak J, Corder C, et al. Peyronie's disease plaque calcification—prevalence, time to identification, and development of a new grading classification. *J Sex Med*. 2013; 10: 3121 – 8.
6. Mayo Clinic. Peyronie's disease. 2020 April 4. Available at: <https://www.mayoclinic.org/diseases-conditions/peyronies-disease/diagnosis-treatment/drc-20353473>. Accessed on July 8, 2020.
7. The Center for Reconstructive Urology. Peyronie's disease symptoms and diagnosis. Available at: <https://www.centerforreconstructiveurology.org/peyronies-disease/symptoms-diagnosis/>. Accessed on July 8, 2020.

Policy History		
#	Date	Change Description
2.7	Effective Date: 08/13/2026	Annual review of criteria was performed, no changes were made
2.6	Effective Date: 08/07/2025	Annual review of criteria was performed, no changes were made
2.5	Effective Date: 08/08/2024	Annual review of criteria was performed, no changes were made
2.4	Effective Date: 08/10/2023	Annual review of criteria was performed, no changes were made
2.3	Effective Date: 08/04/2022	Annual review of criteria was performed, no changes were made
2.2	Effective Date: 08/12/2021	Annual review – no changes made to the criteria at this time
2.1	Effective Date: 08/13/2020	Updated to list when verapamil should not be used first line and to not allow use for cosmetic indications
2.0	Effective Date: 02/06/2020	Annual Review
1.9	Effective Date: 02/14/2019	Updated Step Therapy
1.8	Effective Date: 11/01/2018	Annual Review of Policy
1.7	Effective Date: 11/09/2017	Updated Step Therapy

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1.6	Effective Date: 07/05/2017	UM medical management system update for BCNA and MAPPO <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.5	Effective Date: 05/04/2017	Annual Review										
1.4	Effective Date: 05/05/2016	Criteria update with changes to current step therapy										
1.3	Effective Date: 07/01/2015	UM medical management system update for HMO <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.2	Effective Date: 05/08/2014	Criteria update										
1.1	Effective Date: 01/22/2013	UM medical management system update for BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	No	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	No											
MAPPO	No											
BCNA	No											
1.0	Effective Date: 02/09/2012	-Custom/Clinical Formulary: N/A -Custom formulary chapter: N/A -PartD: Specialty -PartD formulary chapter: Diagnostics and other Micellaneous -Recommended criteria and QL										

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Xiaflex® (Collagenase Clostridium Histolyticum) HCPCS CODE: J0775



This form is to be used by participating physicians to obtain coverage for Xiaflex®. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis/ ICD-9	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Please provide the NPI number for the place of administration: _____
- Has the prescribing physician completed the Xiaflex Xperience training?
☐ Yes ☐ No, Explain _____
- Please check the patient's diagnosis:
☐ Dupuytren's contracture (DC) ☐ Peyronie's disease (PD) ☐ Cellulite ☐ Other _____
- For DC only:**
 - Does the patient have a finger flexion contracture with a palpable cord of at least one finger (other than the thumb) that involves either the metacarpophalangeal (MP) joint or the proximal interphalangeal (PIP) joint?
☐ Yes ☐ No, Explain what Xiaflex is being used for _____
 - Is the administering physician a surgeon who has experience and training in hand surgeries?
☐ Yes ☐ No Comment: _____
- For PD only:**
 - Is Xiaflex being prescribed by or in consultation with a urologist? ☐ Yes ☐ No Comment: _____
 - Does the patient have a palpable plaque? ☐ Yes ☐ No, Explain _____
 - Does the patient have a curvature deformity of at least 30 degrees at start of therapy?
☐ Yes, list the degrees of curvature deformity: _____ ☐ No, list the degrees of curvature deformity: _____
 - What medications has the patient tried and failed?
☐ Pentoxifylline ☐ Verapamil gel ☐ Intralesional verapamil ☐ None ☐ Other: _____
 - Does the patient have any of the following?
☐ The plaque has calcified
☐ Penile curvature greater than 60 degrees, list the degrees of curvature deformity: _____
☐ Plaque has been stable or not changed over that last 6 months
☐ Plaque has been present for greater than 12 months
☐ Other: _____
- Is this the first time the patient has received Xiaflex?
☐ Yes
☐ No, Please specify how many times patient has received Xiaflex and the reason for more injections: _____

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2 Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Xiaflex® Xperience™ physician training ☐ Facility enrolled through Xiaflex® Xperience™ training
Step 3 Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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Revised 5/2/2016; 2/2/2018; 2/16/2018;10/11/2018; 3/8/2019; 10/1/2020