Neighborhood Health Plan OF RHODE ISLAND™
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Xiaflex® (collagenase)
(Intralesional)

Effective Date: 01/01/2020
Review Date: 12/12/2018, 11/27/2019, 1/29/2020, 11/16/2020, 7/22/2021, 5/5/2022, 1/26/2023, 12/07/2023, 01/10/2024, 06/11/2025

Scope: Medicaid, Commercial, Medicare

I. Length of Authorization [1]

- Dupuytren's Contracture: Coverage will be for 3 months and is eligible for renewal for a maximum of 3 injections per joint/cord.
- Peyronie's Disease: Coverage will be for 6 weeks and is eligible for renewal for a maximum of 4 total treatment cycles for each plaque causing the curvature deformity.

II. Dosing Limits

A. Max Units (per dose and over time) [HCPCS Unit]:

Dupuytren's Contracture

- 180 billable units every 28 days

Peyronie's Disease

- 180 billable units every 42 days

III. Summary of Evidence

Xiaflex (collagenase clostridium histolyticum) is an FDA-approved medication primarily used for the treatment of Dupuytren's contracture and Peyronie's disease. The efficacy of collagenase clostridium histolyticum was evaluated two randomized, double-blind, placebo-controlled, multicenter trials in 374 adult patients with Dupuytren's contracture (Studies 1 and 2). At study entry, patients must have had: (1) a finger flexion contracture with a palpable cord of at least one finger (other than the thumb) of 20 to 100 degrees in a metacarpophalangeal (MP) joint or 20 to 80 degrees in a proximal interphalangeal (PIP) joint and (2) a positive "table top test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top. In Studies 1 and 2, the primary endpoint was to evaluate the proportion of patients who achieved a reduction in contracture of the selected primary joint (MP or PIP) to within 0 to 5 degrees of normal, 30 days after the last injection of that joint.on Days 30, 60, or 90 **(**after up to 3 injections). A greater proportion of Xiaflex-treated patients compared to placebo-treated patients achieved the primary endpoint.

The efficacy of collagenase clostridium histolyticum was evaluated in 2 randomized, double-blind, placebo--controlled trials of 832 adult men with Peyronie's disease (Study 1 and Study 2). To be included in the study, patients had to have penile curvature deformity of at least 30 degrees in the stable phase of Peyronie's disease. The coprimary end points in Study 1 and Study 2 were the percent change from baseline to week 52 in penile curvature deformity and the change in the bother domain score of the Peyronie's Disease Questionnaire from baseline to week 52. Patients with Peyronie's disease receiving collagenase clostridium histolyticum had significantly improved penile curvature deformity compared with patients receiving placebo. Common adverse events include injection site reactions, swelling, bruising, and pain.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

- Patient is at least 18 years old; **AND**

Dupuytren's Contracture † Φ [1-3]

- Patient has a palpable cord; **AND**
- Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint; **AND**
- Documentation of a positive "table top test" defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top; **AND**
- Patient has not received a surgical treatment (e.g., fasciectomy, fasciotomy) on the selected joint within 90 days before the first injection; **AND**
- Documentation that the flexion deformity results in functional limitations

Peyronie's Disease † Φ [1,4-6]

- Prescriber is enrolled in the Xiaflex REMS Program; **AND**
- Patient has a palpable plaque on penis; **AND**
- Patient has stable disease with penis curvature deformity of > 30 and < 90 degrees; **AND**
- Patient has intact erectile function (with or without use of medications); **AND**
- Patient does not have a ventral curvature deformity, an isolated hourglass deformity or calcified plaque; **AND**
- The plaque(s) do not involve the penile urethra; **AND**
- Will be used in combination with penile modeling procedures; **AND**
- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**

- The patient has not received a collagenase injection for this condition within the past 6 weeks

† FDA-labeled indication(s); **Φ** Orphan Drug

V. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria identified in section III; **AND**

Dupuytren's Contracture

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include : hypersensitivity reactions (including anaphylaxis), abnormal coagulation, tendon ruptures or other serious injury to the injected extremity, vasovagal reactions (e.g., syncope and presyncope), etc.; **AND**
- Disease response as indicated by reduction in contracture of the selected primary joint compared to baseline; **AND**
- Patient has not exceeded 3 injections per joint/cord; AND
- Patient has not received a collagenase injection for this condition within the past 4 weeks

Peyronie's Disease

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include : hypersensitivity reactions (including anaphylaxis), abnormal coagulation, corporal rupture (penile fracture) or other serious injury to the penis, acute post-injection back pain reactions, vasovagal reactions (e.g., syncope and presyncope etc.; **AND**
- Disease response with treatment as defined by the reduction in curvature of the penis compared to baseline or improvement in Bother domain score of the Peyronie's Disease Questionnaire (PDQ); **AND**
- Patient continues to have penis curvature deformity ≥ 15° after previous treatment cycle(s); **AND**
- Patient has not exceeded 4 total treatment cycles for each plaque causing the curvature deformity; **AND**
- Patient has not received a collagenase injection for this condition within the past 6 weeks

VI. Dosage/Administration

Indication	Dose
Dupuytren's Contracture	Inject 0.58 mg into each palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint. • Up to two joints/cords in the same hand may be treated during a treatment visit. If a patient has other cords with contractures, those cords must be treated at another visit. • May administer up to 3 injections total per cord at approximately 4-week intervals.

Peyronie's Disease	Each treatment cycle entails injection of 0.58 mg into the target plaque on a flaccid penis once on each of two days, 1 to 3 days apart, according to the injection procedure. • For each plaque causing the curvature deformity, up to four total treatment cycles may be administered. Each treatment cycle may be repeated at approximately 6 week intervals. • If the curvature deformity is less than 15 degrees after the first, second, or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles should not be administered

VII. Billing Code/Availability Information

HCPCS Code:

J0775 – Injection, collagenase, clostridium histolyticum, 0.01 mg: 0.01 mg = 1 billable unit

NDC:

Xiaflex 0.9 mg powder for injection: 66887-0003-xx

VIII. References

1. Xiaflex [package insert]. Malvern, PA; Endo Pharmaceuticals, Inc. April 2024. Accessed June 2025.
2. Hurst LC, Badalamente MA, Hentz VR et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med. 2009; 361:968-79.
3. Hurst LC, Badalamente MA, Wang ED. Injectable clostridial collagenase: striving toward non- operative treatment options for fibroproliferative disorders. Available at http://www.aaos.org/research/committee/research/Kappa/KD2009_Hurst.pdf
4. Gelbard M, Goldstein I, Hellstrom WJ, et al. Clinical efficacy, safety and tolerability of collagenase clostridium histolyticum for the treatment of peyronie disease in 2 large double-blind, randomized, placebo controlled phase 3 studies. J Urol. 2013 Jul; 190(1):199-207. doi: 10.1016/j.juro.2013.01.087. Epub 2013 Jan 31.
5. Nehra A, Alterowitz R, Culkin DJ, et. al. Peyronie's Disease: AUA Guideline. J Urol. 2015 Sep;194(3):745-53. doi: 10.1016/j.juro.2015.05.098.
6. Bella AJ, Lee JC, Grober ED, et al. 2018 Canadian Urological Association guideline for Peyronie's disease and congenital penile curvature. Can Urol Assoc J. 2018 May; 12(5): E197–E209.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M72.0	Palmar fascial fibromatosis [Dupuytren]
N48.6	Induration penis plastica

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Xiaflex was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Xiaflex according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.