

Xiaflex® (collagenase) (Intralesional)

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I. Length of Authorization ¹

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Xiaflex 0.9mg injection: 2 vials per 28 days

B. 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. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **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°; **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 a calcified plaque; **AND**
- Plaque(s) do not involve the penile urethra; **AND**
- Will be used in combination with penile modeling procedures

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the 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 with treatment as defined 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 $\geq 15^\circ$ 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

V. Dosage/Administration¹

Indication	Dose
Dupuytren's Contracture	<p>Inject 0.58 mg into each palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint, according to the injection procedure.</p> <ul style="list-style-type: none"> • 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	<p>For each treatment cycle, inject 0.58 mg into the target plaque on a flaccid penis for two injections, separated by 1 to 3 days, according to the injection procedure.</p> <ul style="list-style-type: none"> • For each plaque causing the curvature deformity, up to 4 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° after the first, second, or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles should not be administered.

VI. 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

VII. References

1. Xiaflex [package insert]. Malvern, PA; Endo Pharmaceuticals, Inc.; July 2023. Accessed October 2023.
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: <https://www.cms.gov/medicare-coverage-database/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 GBA, 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
15	KY, OH	CGS Administrators, LLC