

Approved by: Optum Medical and Pharmacy Subcommittee	Effective Date: 10/01/2026
Clinical Policy Document: Collagenase clostridium histolyticum (Xiaflex)	Date Approved: 10/01/2026
Reference #: MC/PC004	Replaces Effective Clinical Policy Dated: N/A

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PLANS IN SCOPE

Aspirus Health Plan

BACKGROUND & PURPOSE

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Background

Collagenase clostridium histolyticum (Xiaflex®) is an injectable enzymatic therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of Dupuytren's contracture and Peyronie's disease. Both conditions are fibroproliferative disorders characterized by abnormal collagen deposition that results in functional impairment.

Dupuytren's contracture is a progressive disorder of the palmar fascia leading to palpable cords and fixed flexion deformities of the fingers, most commonly affecting the metacarpophalangeal (MP) and proximal interphalangeal (PIP) joints. Historically, treatment options included surgical fasciectomy or percutaneous needle aponeurotomy. Xiaflex provides a non-surgical alternative supported by randomized controlled trials, long-term extension studies, and contemporary systematic reviews demonstrating improvement in joint contracture and hand function.

Peyronie's disease is an acquired fibrotic disorder of the tunica albuginea characterized by plaque formation, penile curvature, and potential sexual dysfunction. Xiaflex is the only FDA-approved pharmacologic therapy for Peyronie's disease and is supported by Phase 3 randomized controlled trials and professional society guidelines demonstrating clinically meaningful reductions in curvature and symptom burden.

Purpose

The purpose of this policy is to support consistent, evidence-based coverage determinations for collagenase clostridium histolyticum (Xiaflex®) in alignment with FDA labeling, peer-reviewed clinical evidence, and commercial utilization-management standards.

Please refer to the member's benefit document for specific coverage information. In the event of any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the member's benefit plan document will govern.

COVERAGE INDICATIONS:

Xiaflex is prescribed and administered by a healthcare provider experienced in injection procedures appropriate to the treated condition.

Dupuytren's Contracture

Xiaflex is considered medically necessary when all of the following criteria are met:

- Documented diagnosis of Dupuytren's contracture
- Presence of a palpable cord in the affected hand
- Contracture involves a metacarpophalangeal (MCP) joint and/or proximal interphalangeal (PIP) joint

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- Flexion contracture of at least 20 degrees in the affected joint
- Documented functional limitation of the hand attributable to the contracture
- Member is 18 years of age or older

Peyronie's Disease

Xiaflex is considered medically necessary when all of the following criteria are met:

- Documented diagnosis of Peyronie's disease
- Stable disease (e.g., no progression in curvature or pain over a defined duration)
- Penile curvature is greater than 30 degrees and less than 90 degrees
- Presence of a palpable plaque
- Intact erectile function, with or without pharmacologic assistance
- Member is 18 years of age or older
- For treatment of Peyronie's disease, Xiaflex must be prescribed and administered by a healthcare provider experienced in the treatment of male urological diseases who has completed the required Xiaflex training and is certified in the Xiaflex REMS Program. Xiaflex must be administered at a healthcare site certified in the Xiaflex REMS Program.

Dosing

Dupuytren's Contracture

Xiaflex is administered at a dose of 0.58 mg per injection into a palpable Dupuytren's cord causing contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint.

- Up to two joints in the same hand may be treated during a treatment visit, including two palpable cords affecting two joints or one palpable cord affecting two joints in the same finger, with injections administered at two separate locations. Separate vials and syringes should be used for each injection.
- A maximum of three injections per cord may be administered
- Injections are administered at approximately 4-week intervals, consistent with FDA labeling

Peyronie's Disease

- Each treatment cycle consists of two Xiaflex 0.58 mg injections administered 1 to 3 days apart and one clinician-performed penile modeling procedure performed 1 to 3 days after the second injection.
- Treatment cycles may be repeated at approximately 6-week intervals. Patients should also perform at-home penile modeling as instructed by the treating provider.
- For each plaque causing the curvature deformity, a treatment course may include up to four treatment cycles. The safety of more than one treatment course has not been established.

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- If the curvature deformity is less than 15 degrees after the 1st, 2nd, or 3rd treatment cycle, or if further treatment is not clinically indicated, subsequent cycles should not be administered.
- Xiaflex must be administered in accordance with REMS requirements

Safety Monitoring and Requirements

- Xiaflex must be administered in accordance with FDA labeling
- Patients must be counseled regarding potential adverse events
- Monitoring for localized reactions and serious complications (e.g., tendon rupture, corporal rupture) is required
- REMS participation is mandatory for Peyronie's disease

Exclusions

Coverage is not provided for:

- Use outside FDA-approved indications
- Plaques involving the penile urethra (in Peyronie's disease)
- Cosmetic or investigational use
- Failure to comply with Xiaflex REMS requirements
- History of hypersensitivity to collagenase clostridium histolyticum or any component of the product

Other exclusions/considerations include:

- Pregnancy: Xiaflex has not been studied in pregnant individuals, and there are no adequate or well-controlled studies to inform fetal risk. Use during pregnancy is not recommended due to lack of information in this population.
 - Lactation: It is unknown whether collagenase clostridium histolyticum is excreted in human milk, and the effects on a breastfed infant have not been established. Use during lactation is not recommended due to lack of information in this population.
 - Members with a known bleeding disorder or abnormal coagulation, including but not limited to:
 - Congenital or acquired coagulation disorders
 - Use of anticoagulant therapy (excluding low-dose aspirin) that cannot be safely held
- Rationale: Xiaflex is associated with an increased risk of bleeding, bruising, and hematoma at the injection site, and the FDA labeling advises caution in patients with bleeding disorders. Use in this population is not recommended unless the potential benefit clearly outweighs the risk.

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Emerging Therapies

Alternative formulations or non-approved uses of collagenase clostridium histolyticum are under investigation. At this time, use outside FDA-approved indications is considered investigational for coverage purposes.

Medical Records Documentation

Benefit coverage is determined by review of member-specific benefit plan information and all applicable laws. Medical records documentation may be required to assess if the member meets criteria; however, provision of records does not guarantee coverage. Current requirements for Xiaflex include, but may not be limited to:

- Degree of curvature or contracture
- Method of measurement
- Functional impairment

DEFINITIONS

Risk Evaluation and Mitigation Strategy (REMS):

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program required by the U.S. Food and Drug Administration (FDA) for certain medications with serious or potentially serious safety risks, when the FDA determines that additional measures beyond standard prescribing information are necessary to ensure that the benefits of the drug outweigh its risks.

A REMS may include one or more of the following components, depending on the specific safety concern associated with the medication:

- Medication Guides or patient education materials
- Communication plans for healthcare providers
- Elements to Assure Safe Use (ETASU), such as:
 - Prescriber, pharmacy, or healthcare setting certification
 - Patient enrollment or informed consent
 - Required monitoring, testing, or follow-up
 - Restrictions on prescribing, dispensing, or administration

REMS programs are drug-specific, legally enforceable, and may apply at the time of initial FDA approval or be imposed post-approval if new safety information emerges. Only a limited number of FDA-approved drugs require a REMS.

For Peyronie's disease, collagenase clostridium histolyticum (Xiaflex®) is subject to an FDA-required REMS that restricts administration to certified prescribers and settings due to the risk of serious penile injury, including corporal rupture

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APPLICABLE CODES

Note: The code list below is provided for guidance. Code coverage will depend on the coverage guidelines above.

Code Type	Code	Description
HCPCS	J0775	Collegenase clostridium histolyticum, 0.01 mg

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POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
10/01/2026	Initial Policy Development	Optum Coverage Policy Committee

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Dupuytren's Contracture:

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Regulatory/Labeling

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Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).