

Medical Policy:

XIAFLEX® (collagenase clostridium histolyticum)

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|-----------------|-------------|
| MG.MM.PH.350 | January 2, 2024 | |

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Xiaflex® (collagenase clostridium histolyticum) is a biologic injectable that enzymatically breaks down collagen when injected directly into a Dupuytren’s cord. This can result in contracture reduction and range of motion improvement.

Dosing Limits [Medical Benefit]

Max units (per dose and over time):

- Dupuytren’s contracture:
 - 58 billable units per cord up to 3 times approximately 4 weeks apart (180 Billable units every 28 days)
- Peyronie’s Disease:
 - 58 billable units on each of 2 days 1-3 days apart every 6 weeks a maximum of 4 times (8 injections) (180 Billable units every 42 days)

Guideline

Xiaflex (collagenase clostridium histolyticum) is considered medically necessary for the following diagnosis when the subsequent criteria are met:

Dupuytren's Contracture:

1. Patient is 18 years of age or older; **AND**
2. Patient has a palpable cord; **AND**
3. Documented flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint; **AND**
4. 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**
5. Documentation that the flexion deformity results in functional limitations

Peyronie's Disease:

1. Patient is 18 years of age or older; **AND**
2. Patient has palpable plaque on the penis; **AND**
3. Patient has stable disease with penis curvature deformity of > 30° and < 90°; **AND**
4. Patient has intact erectile function (with or without use of medications); **AND**
5. Patient does not have isolated hourglass deformity or calcified plaque; **AND**
6. Plaque(s) do not involve the penile urethra; **AND**
7. Will be used in combination with penile modeling procedures
8. Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; **AND**
9. Patient has not received a collagenase injection for this condition within the past 6 weeks; **AND**

MEDICAID PATIENTS ONLY: In ADDITION to meeting the Medical Necessity Criteria:

1. Erectile Dysfunction Verification System (EDVS) status has been checked; **AND**
2. If patient is on the sex offender list and the request is approved by the medical director, that approval must be limited to a maximum of 30 days' supply. Renewal must be requested every 30 days with verification of Erectile Dysfunction Verification System (EDVS) status upon every request every 30 days

Coverage for Xiaflex may be renewed for the following diagnosis when subsequent criteria are met:

1. Peyronie's Disease:

- A. Patient's curvature deformity is 15 degrees or greater; **AND**
- B. Erectile Dysfunction Verification System (EDVS) status has been checked (**Medicaid patients only**)
- C. Absence of unacceptable toxicity from the drug. (*Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions, abnormal coagulation, corporal rupture (penile fracture) or other serious injury to the penis, acute post-injection back pain reactions, etc.*); **AND**
- D. 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**
- E. Patient has not exceeded 4 total treatment cycles for each plaque causing the curvature deformity; **AND**
- F. Patient has not received a collagenase injection for this condition within the past 6 weeks

2. Dupuytren's Contracture

- A. Absence of unacceptable toxicity from the drug. (*Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions, abnormal coagulation, tendon ruptures or other serious injury to the injected extremity, etc.*); **AND**

- B. Disease response with treatment as defined by reduction in contracture of the selected primary joint compared to baseline; **AND**
- C. Patient has not exceeded 3 injections per joint/cord; **AND**
- D. Patient has not received a collagenase injection for this condition within the past 4 weeks

Limitations/Exclusions

1. Approval will be granted for 12 weeks for a diagnosis of Dupuytren’s Contracture per cord and may not be renewed (for non-Medicaid members)
2. Subsequent approvals for a diagnosis of Dupuytren’s Contracture will require a new authorization
3. Approval will be granted for 6 weeks for a diagnosis of Peyronie’s Disease and may be renewed a maximum of 4 times (for non-Medicaid members)
4. As serious complications or damage may occur, Xiaflex should only be administered by a health care professional experienced with hand injections (for Dupuytren’s contracture) or urologists (for Peyronie’s disease) who have received certification in the Xiaflex Risk Evaluation and Mitigation Strategy (REMS) Program.

Applicable Procedure Codes

| Code | Description |
|-------|--|
| 20550 | Injection(s); single tendon sheath, or ligament, aponeurosis (e.g., plantar "fascia") |
| 20527 | injection, enzyme (e.g., collagenase), palmar fascial cord (i.e., Dupuytren's contracture) |
| 26341 | Manipulation, palmar fascial cord (i.e., Dupuytren's cord), post-enzyme injection (e.g., collagenase), single cord |
| 29130 | Application of finger splint; static |
| 54200 | Injection procedure for Peyronie disease; |
| 54235 | Injection of corpora cavernosa with pharmacologic agent(s) (e.g., papaverine, phentolamine) |
| 96372 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |
| J0775 | Injection, collagenase, clostridium histolyticum, 0.01 mg |

Applicable NDCs

| Code | Description |
|---------------|--|
| 66887-0003-01 | XIAFLEX 0.9MG Solution Reconstituted J0775 Injection, collagenase, clostridium histolyticum, 0.01 mg |

ICD-10 Diagnoses

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

Revision History

| Company(ies) | DATE | REVISION |
|-----------------------------|----------|---|
| EmblemHealth & ConnectiCare | 1/2/2024 | Annual Review: Updated dosing limits Initial Criteria: <u>Dupuytren’s Contracture:</u> |

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|-----------------------------|------------|--|
| | | <p>Removed: "Considerable function impairment as demonstrated by documentation of flexion deformities >20 degrees at the metacarpophalangeal (MCP) joint or proximal interphalangeal (PIP) joint" Replaced with: "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 Documentation that the flexion deformity results in functional limitations"</p> <p><u>Peyronie's Disease:</u> Removed: "Patient has a curvature deformity of at least 30 degrees at the start of therapy AND" Replaced with: "Patient has stable disease with penis curvature deformity of > 30° and < 90°;" Added: "Patient has not exceeded 4 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; AND" Renewal Criteria: <u>Peyronie's Disease:</u> Added: "Absence of unacceptable toxicity from the drug. (Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions, abnormal coagulation, corporal rupture (penile fracture) or other serious injury to the penis, acute post-injection back pain reactions, 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 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"</p> <p><u>Dupuytren's Contracture</u> Added: "Absence of unacceptable toxicity from the drug. (Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions, abnormal coagulation, tendon ruptures or other serious injury to the injected extremity, 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"</p> |
| EmblemHealth & ConnectiCare | 3/14/2023 | Annual Review: Peyronie's Disease Criteria: Added: Patient has intact erectile function (with or without use of medications); AND Patient does not have isolated hourglass deformity or calcified plaque; AND Plaque(s) do not involve the penile urethra; AND Will be used in combination with penile modeling procedures |
| EmblemHealth & ConnectiCare | 10/20/2022 | Added EDVS check and max 30 days' supply for Medicaid patients only |
| EmblemHealth & ConnectiCare | 3/31/2022 | Removed "Patient's with recent onset disease with signs of inflammation (tenderness, nodules, or tenosynovitis) have had an ineffective trial with a corticosteroid injection; AND" from initial criteria. Transferred policy to new template with updated pharmacy policy number. |
| EmblemHealth & ConnectiCare | 12/30/2020 | Annual Review: No policy changes |

References

1. Anderson, Bruce C, Sheon Robert P. Dupuytren's contracture. In: UpToDate, edited by Zacharia Isaac, published by UpToDate in Waltham, MA. 2010.
2. FDA. Xiaflex Prescribing Information. Revised October, 2019. Accessed March 2022.
3. Specialty-matched clinical peer review.