Medical Policy:

XIAFLEX® (collagenase clostridium histolyticum)

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

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: Dupuytren's Contracture:

		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" Peyronie's Disease: 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: Peyronie's Disease: 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" Dupuytren's Contracture 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"
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.