Pharmacy Medical Policy
Injectable Clostridial Collagenase for Fibroproliferative Disorders

Table of Contents
- Policy: Commercial
- Coding Information
- Information Pertaining to All Policies
- Policy: Medicare
- Description
- References
- Authorization Information
- Policy History

Policy Number: 225
BCBSA Reference Number: 5.01.19

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also submit requests for exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com.

This medication is not covered by the pharmacy benefit. It is covered by the Medical Benefit or as a Home Infusion Therapy.

Injection of clostridial collagenase (up to 3 injections at 4-week intervals per lesion) is covered for the treatment of adults with Dupuytren’s contracture when all of the following conditions are met:
- There is a palpable cord, **AND**
- There is functional impairment, **AND**
- There are fixed-flexion contractures of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more (excluding the thumb), **AND**
- The injection is administered only by a physician credentialed in hand surgery (e.g., Orthopedics, Plastic Surgery), or by a board certified Rheumatologist experienced in injection procedures of the hand and in the treatment of patients with Dupuytren’s contracture.

Injection of clostridial collagenase (up to 8 injections at 6-week intervals per lesion) is covered for the treatment of adult males with Peyronie's disease when all of the following conditions are met:
- There is a palpable plaque causing the curvature, **AND**
- There is curvature deformity of at least 30 degrees or more at the start of therapy, **AND**
- The injection is administered only by a physician board certified or board eligible in urology.
Note: Collagenase clostridium histolyticum can be administered in an office setting.

Injectable clostridial collagenase is considered investigational for all other indications including, but not limited to, adhesive capsulitis.

Medicare HMO BlueSM and Medicare PPO BlueSM Members
BCBSMA covers injection of clostridial collagenase for the treatment of adults with Dupuytren’s contracture in accordance with the local Medicare guidelines when all of the following conditions are met:

- There is a palpable cord, AND
- There is functional impairment, AND
- There are fixed-flexion contractures of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more (excluding the thumb), AND
- The injection is administered only by a physician credentialed in hand surgery (e.g., Orthopedics, Plastic Surgery), or by a board certified Rheumatologist experienced in injection procedures of the hand and in the treatment of patients with Dupuytren's contracture.

Note: Collagenase clostridium histolyticum can be administered in an office setting.

We do not cover injection of clostridial collagenase in accordance with local Medicare guidelines for contractures of most body parts.

We do not cover the use of ultrasound for injection of clostridial collagenase in accordance with local Medicare guidelines.

Local Coverage Determination (LCD) for Collagenase Clostridium Histolyticum (L31333)
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=31333&ContrId=208&ver=3&ContrVer=1&ContrctrSelected=208*1&Contrctr=208&name=NHIC%2c+Corp.+(14202%2c+MAC+-+Part+B)&s=24&bc=AggAAAIAAAAA&

Individual Consideration
All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Instructions
- Prior authorization is required for all outpatient sites of service
- For all outpatient sites of service, physicians may fax or mail the attached form to the address above. For all outpatient sites of service, physicians may also submit authorization requests via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com.

PPO and Indemnity Authorization Instructions
- Prior authorization is required when this medication is processed under the home infusion therapy benefit.
- Prior authorization is not required when this medication is purchased by the physician and administered in the office in accordance with this medical policy.
Physicians may also fax or mail the attached form to the address above.

Physicians may also submit authorization requests via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20527</td>
<td>Injection, enzyme (eg, collagenase), palmar fascial cord (i.e., Dupuytren’s contracture)</td>
</tr>
<tr>
<td>26341</td>
<td>Manipulation, palmar fascial cord (i.e., Dupuytren’s cord), post enzyme injection (e.g., collagenase), single cord</td>
</tr>
</tbody>
</table>

### HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0775</td>
<td>Injection, collagenase clostridium histolyticum, 0.01 mg</td>
</tr>
</tbody>
</table>

### ICD-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>607.85</td>
<td>Peyronie’s disease</td>
</tr>
<tr>
<td>726.0</td>
<td>Adhesive capsulitis of shoulder</td>
</tr>
<tr>
<td>728.6</td>
<td>Contracture of palmar fascia</td>
</tr>
</tbody>
</table>

### ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N48.6</td>
<td>Induration penis plastica</td>
</tr>
<tr>
<td>M72.0</td>
<td>Palmar fascial fibromatosis [Dupuytren]</td>
</tr>
<tr>
<td>M75.00</td>
<td>Adhesive capsulitis of unspecified shoulder</td>
</tr>
<tr>
<td>M75.01</td>
<td>Adhesive capsulitis of right shoulder</td>
</tr>
<tr>
<td>M75.02</td>
<td>Adhesive capsulitis of left shoulder</td>
</tr>
</tbody>
</table>

### Description
Clostridial collagenase is a bacterial collagenase derived from Clostridium histolyticum. Collagenases are enzymes that digest native collagen and are being evaluated for treatment of fibroproliferative disorders, such as Dupuytren’s contracture and Peyronie’s disease.

Injection with clostridial collagenase is intended to provide a non-operative treatment option for fibroproliferative disorders. Fibrotic tissue disorders, characterized by excessive collagen deposits, can affect the musculoskeletal system causing pain and limitation of movement and reduction of joint range of motion.
An example of an injectable clostridial collagenase for fibroproliferative disorders is Xiaflex from Auxilium Pharmaceutical Inc. “All injectable clostridial collagenase for fibroproliferative disorders are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy statement.

Summary
In summary, the evidence from clinical trials suggests that injectable clostridial collagenase provides short-term release of contracture in Dupuytren’s disease. While evidence of long-term recurrence rates is limited, this may be an appropriate treatment option in adult patients with a palpable cord based on short-term evidence of effectiveness and a preponderance of agreement from clinical input. Therefore, injectable clostridial collagenase may be considered medically necessary as an alternative to surgical options. A comparison of overall outcomes compared to surgical intervention may be useful; however, studies with direct comparisons are not available. Potentially serious adverse events also warrant further investigation.

Small trials demonstrated short-term improvement in patients with Peyronie’s disease. Larger trials directly comparing outcomes with current treatment options are required. Therefore, based on available evidence and clinical input, injection of this agent is considered investigational for all other treatment indications, including Peyronie’s disease and adhesive capsulitis.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>3/2014</td>
<td>Added New FDA indication of Peyronie’s Disease.</td>
</tr>
<tr>
<td>1/2014</td>
<td>Updated ExpressPAth language. Also, New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>1/15/2011</td>
<td>Updated to include coverage for Medicare HMO Blue and Medicare PPO Blue when medical necessity criteria are met.</td>
</tr>
<tr>
<td>5/1/2010</td>
<td>Medical policy 225 created.</td>
</tr>
</tbody>
</table>

References
Xiaflex (Collagenase) Prior Authorization Form
Please complete and fax to: (888)641-5355
Please contact Pharmacy Operations with questions at (800)366-7778
If the patient is a BCBSMA employee, please fax the form to (617)246-4013

For Home Infusion Authorizations:

<table>
<thead>
<tr>
<th>Company Name:</th>
<th>Contact:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone:</td>
<td>Provider #:</td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Patient Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient BCBSMA ID#:</td>
<td>Patient DOB:</td>
</tr>
<tr>
<td>Physician Name:</td>
<td>Physician Telephone:</td>
</tr>
<tr>
<td>Physician Address:</td>
<td>Physician Fax:</td>
</tr>
</tbody>
</table>

For Outpatient Administration:

<table>
<thead>
<tr>
<th>Servicing Provider:</th>
<th>Name:</th>
<th>NPI #:</th>
<th>Requesting Provider:</th>
<th>Name:</th>
<th>NPI #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td></td>
<td></td>
<td>Phone:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
<td></td>
<td>Fax:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Person:</td>
<td></td>
<td></td>
<td>Contact Person:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Name:</td>
<td></td>
<td></td>
<td>Patient Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient BCBSMA ID#:</td>
<td></td>
<td></td>
<td>Patient DOB:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please provide information as requested below:

Drug: ____________________ Dose: ____________________ Frequency: ____________________

Route of administration: ____________________ Dates of Service: ____/____/____ to ____/____/____

Diagnosis: ____________________ ICD-9 code: ____________________

1. Is there a palpable cord? (please circle)  Yes  No
2. Is there is functional impairment? (please circle)  Yes  No
3. Please indicate below the affected joint, degree of flexion, and frequency of contracture:

________________________________________________________________________

4. What is the prescriber’s specialty?

________________________________________________________________________

5. Please provide any additional clinical information that you would like considered with this request:

________________________________________________________________________

Physician Signature: ____________________

☐ Copy of a signed prescription is required for all Home Infusion request