I. POLICY

It is the policy of MedStar Health, Inc. to cover Xiaflex (Collagenase Clostridium Histolyticum) when it is medically necessary (Refer to CRM .015.MH-Medical Necessity policy) as detailed in this policy and covered under the member’s specific benefit plan.

II. DEFINITIONS

Dupuytren’s contracture -- also abbreviated as Dupuytrens, is a benign thickening of the palm's deep connective tissue (fascia).

Fasciectomy -- surgical removal of the fibrous tissue beneath the skin.

Percutaneous needle aponeurotomy (fasciotomy) -- this technique uses needles to puncture the contracting (blocking) Dupuytrens cord and thus weaken it until it can be broken by mechanical force. It is a minimally invasive, outpatient procedure.

Peyronie’s disease (PD) – a fibrotic disease of the penis which can result in penile curvature/deformity, narrowing, shortening, hinging, and sexual dysfunction.

III. PURPOSE

The purpose of this policy is to provide the indications for coverage of Xiaflex® (Collagenase Clostridium Histolyticum).
IV. SCOPE

This policy applies to various MedStar Health, Inc. departments.

V. PROCEDURE

A. Medical Description / Background

Xiaflex® (collagenase clostridium histolyticum) is approved by the Food and Drug Administration (FDA) non-surgical treatment option for adult patients with Dupuytren’s contracture and Peyronie’s Disease.

Dupuytren’s contracture is a benign connective tissue disorder that results from excessive collagen deposits in the palm of the hand. The deposits begin as nodules but progress into ropelike cords of fibrous tissue which can cause flexion of the proximal interphalangeal (PIP) and metacarpophalangeal (MCP) joints of the fingers. The progression of these cords causes the affected fingers to curl towards the palm making extension of these fingers difficult or impossible. The cause of the disorder is unknown and thought to be inherited. It can affect both hands and usually starts with the 4th and 5th digits. Treatment consists of corticosteroid injections into the affected tendon sheaths, analgesics for pain relief, physical therapy, or percutaneous needle aponeurotomy (fasciotomy). Surgery (open fasciectomy) may be required depending on the extent of the deformity caused by the contracture and how it affects the patient’s activities of daily living.

Xiaflex® is a protein whose enzymes work by breaking down the collagen which reduces the contracture and may improve range of motion in the affected joints. This procedure is followed-up with manipulation/stretching of the involved cord 24 hours after the injection unless the cord has ruptured. Each injection contains 0.58 mg of Xiaflex®, must be performed in a physician’s office, and does not require anesthesia. The correct injection site must be chosen and care must be taken to inject the drug without piercing the cord. Injection of the drug into tendons, nerves, or blood vessels may result in permanent injury such as tendon rupture or ligament damage. The patient has to elevate the treated hand for several hours after the procedure and may have to wear a splint at bedtime for several months. Serious adverse reactions include tendon rupture, peripheral edema and pain in the treated extremity. Further long-term studies are needed to establish data on recurrences after use of Xiaflex® and to compare all available treatment methods for this disease.
Peyronie’s Disease is caused by scar tissue that develops under the skin of the penis. This scar tissue causes an abnormal bend during erection and can cause problems such as bothersome symptoms during intercourse. Xiaflex is believed to work for Peyronie’s disease by breaking down the buildup of collagen (a structural protein in connective tissue) that causes the curvature deformity. A treatment course for Peyronie’s disease consists of a maximum of four treatment cycles. Each treatment cycle consists of two Xiaflex injection procedures (in which Xiaflex is injected directly into the collagen-containing structure of the penis) and one penile modeling procedure performed by the health care professional. When prescribed for the treatment of Peyronie’s disease, Xiaflex is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risks of serious adverse reactions, including a penile fracture (rupture of one of the penile bodies within the penile shaft, also known as corporal rupture) and other serious penile injury. Xiaflex for the treatment of Peyronie’s disease should be administered by a health care professional who is experienced in the treatment of male urological diseases.

B. Indications

Xiaflex is considered medically necessary and is therefore covered for either of the following indications:

- For adults with documented Dupuytren’s contracture with a palpable cord;
- For males with documented Peyronie’s disease with penile curvature of ≥30 degrees at the start of therapy.

C. Limitations

General Limitations

- Xiaflex is not covered for any other indication
- Member should be free of any chronic muscular, neurological or neuromuscular disorder affecting the hands
- Should be used with caution for members on anticoagulants (except for low-dose aspirin)
- The safety and effectiveness for use in children less than 18 years of age has not been established
- The physician must have completed the manufacturer’s required training course per the FDA’s requirement as part of the Xiaflex® Risk Evaluation and Mitigation Strategy (REMS)
- Redirection of the needle in the subcutaneous or intralesional tissue does not constitute a separate injection.
Limitations Specific to Treatment of Dupuytren’s Contracture

- The injection should only be performed by a physician experienced in injection procedures of the hand and in the treatment of this type of contracture
- Up to two joints in the same hand may be treated during a treatment visit
- Injections and finger extension procedures may be administered up to three times per cord at approximately four week intervals.
- Only one initial evaluation and management (E&M) service visit may be billed for the series of injections used to treat the entire Dupuytren’s contracture of one hand.
- E&M services billed on the same day of service as an injection must be for a significant and separately identifiable service unless it is the initial evaluation for the series of injections as indicated above.
- More than two follow-up visits per joint level injection of a cord may be subject to review. Documentation should be kept on file and available upon request.
- The same physician should perform the injection and the manipulation/stretching procedure for Dupuytren’s contracture.

Limitations Specific to Treatment of Peyronie’s Disease

- Injections for Peyronie’s disease are limited to four treatment cycles. Each treatment cycle consists of two Xiaflex injections and one penile remodeling procedure performed by a health care professional.

D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0775</td>
<td>Injection, collagenase, clostridium Histolyticum, 0.01 mg</td>
</tr>
<tr>
<td>20527</td>
<td>Injection, enzyme (e.g., 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>
<tr>
<td>54200</td>
<td>Injection procedure for Peyronie disease</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
</tr>
</thead>
</table>

UPMC Health Plan and Evolent Health provide administrative functions and services on behalf of MedStar Health, Inc. and its affiliates.

Proprietary and Confidential Information of UPMC Health Plan
© 2015 UPMC All Rights Reserved
E. Variations

N/A

F. Quality Audit

Quality Audit monitors policy compliance and/or billing accuracy at the request of the MedStar Health, Inc.

G. Records Retention

Records Retention for documents, regardless of medium, is provided within the MedStar Health Policy HS-LE0009 Records Retention, Management and Retirement, and as indicated in the Insurance Services Division Policy and Procedure CORP.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. References

Medical Literature/Clinical Information


Disclaimer:

MedStar Health, Inc. medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health, Inc. and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health, Inc. reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of UPMC Health Plan. Any sale, copying, or dissemination of said policies is prohibited.