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| Policy Title: | Xiaflex (Clostridium histolyticum) (Intralesional) | | |
| | | Department: | PHA |
| Effective Date: | 01/01/2020 | | |
| Review Date: | 12/12/2018, 11/27/2019, 1/29/20 | | |
| Revision Date: | 12/12/2018, 11/27/2019, 1/29/20 | | |

Purpose: To support safe, effective and appropriate use of Xiaflex (Clostridium histolyticum).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Xiaflex (Clostridium histolyticum) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Xiaflex (Clostridium histolyticum) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria for Dupuytren's contracture:

- Patient is at least 18 years of age; AND
- Patient has a documented diagnosis of Dupuytren's contracture; AND
- Patient has a palpable cord; AND
- 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;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Initial Criteria for Peyronie's Disease:

- Patient is at least 18 years of age; AND
- Documented diagnosis of Peyronie's disease with a palpable plaque; AND
- Patient has penis curvature deformity of >30 degrees and <90 degrees; AND

- Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; AND
- The patient has not received a Xiaflex injection for this condition within the past 6 weeks;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Continuation of therapy:

- Patient is tolerating treatment; AND
- For Dupuytren's contracture:
 - Disease response as indicated by reduction in contracture of the selected primary joint compared to baseline; AND
 - Patient has not exceeded 3 injections per joint/cord.
- For Peyronie's Disease:
 - Patient has not exceeded 4 treatment cycles for each plaque causing the curvature deformity; AND
 - Disease response as indicated by improvement in penile curvature deformity; AND
 - The patient has not received a Xiaflex injection for this condition within the past 6 weeks;
 - Patient has penis curvature deformity of at least 15 degrees after the previous treatment cycle

Coverage durations:

- Dupuytren's contracture: 3 months and can be renewed up to a maximum of 3 injections per cord
- Peyronie's Disease: 1 month and can be renewed up to a maximum of 4 treatment cycles

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

| Indication | Dose | Maximum dose (1 billable unit = 0.1 mg) |
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| Dupuytren's contracture | Inject 0.58 mg into each palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint. Up to two joints/cords in the same hand may be treated during a treatment visit. If a patient has other cords with contractures, those cords must be treated at another visit. May administer up to 3 injections total per cord at approximately 4-week intervals | 180 billing units every 28 days |
| Peyronie's Disease | Each treatment cycle entails injection of 0.58 mg into the target plaque once on each of two days, 1 to 3 days apart, according to the injection procedure. | 180 billing units every 42 days |

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| | <p>For each plaque causing the curvature deformity, up to four total treatment cycles may be administered. Each treatment cycle may be repeated at approximately 6 week intervals.</p> <p>If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if further treatment is not clinically indicated, then subsequent treatment cycles should not be administered</p> | |
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Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

| HCPCS/CPT Code | Description |
|----------------|--|
| 11900 | Inject skin lesions, up to and including 7 lesions |
| J0775 | Injection, collagenase, clostridium histolyticum, 0.01mg |

References:

1. Xiaflex (collagenase clostridium histolyticum) package insert. Malvern, PA: Auxilium Pharmaceuticals, Inc.; June 2018.
2. Hurst LC, Badalamente MA, Hentz VR et al. Injectable collagenase clostridium histolyticum for Dupuytren's contracture. N Engl J Med. 2009; 361:968-79.
3. Hurst LC, Badalamente MA, Wang ED. Injectable clostridial collagenase: striving toward non-operative treatment options for fibroproliferative disorders. Available at http://www.aaos.org/research/committee/research/Kappa/KD2009_Hurst.pdf

4. Gelbard M, Goldstein I, Hellstrom WJ, et al. Clinical efficacy, safety and tolerability of collagenase clostridium histolyticum for the treatment of peyronie disease in 2 large doubleblind, randomized, placebo controlled phase 3 studies. J Urol. 2013 Jul; 190(1):199-207. doi: 10.1016/j.juro.2013.01.087. Epub 2013 Jan 31.
5. Nehra A, Alterowitz R, Culkin DJ, et. al. Peyronie's Disease: AUA Guideline. J Urol. 2015 Sep;194(3):745-53. doi: 10.1016/j.juro.2015.05.098.
6. Bella AJ, Lee JC, Grober ED, et al. 2018 Canadian Urological Association guideline for Peyronie's disease and congenital penile curvature. Can Urol Assoc J. 2018 May; 12(5): E197–E209.