

## **MP.097.MPC Xiaflex (Collagenase Clostridium Histolyticum)**

Maryland Physicians Care considers **Xiaflex (Collagenase Clostridium Histolyticum)** medically necessary for the following indications:

- For adults with documented Dupuytren's contracture with a palpable cord; or
- For adult males with documented Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

### **General Limitations**

- Xiaflex is not covered for any other indication, including adhesive capsulitis
- 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)
- It is not known if Xiaflex is safe and effective in children under the age of 18
- 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 administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's 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**

- Xiaflex is only available for the treatment of Peyronie's disease through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)

## MP.097.MPC Xiaflex (Collagenase Clostridium Histolyticum)

Policy Number: MP.097.MPC

Last Review Date: 02/20/2025

Effective Date: 03/01/2025

- 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.

### Codes

#### CPT Codes / HCPCS Codes / ICD-10 Codes

Code	Description
J0775	Injection, collagenase, clostridium Histolyticum, 0.01 mg
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
54200	Injection procedure for Peyronie disease

#### ICD-10 codes covered if selection criteria are met:

M72.0	Palmar fascial fibromatosis [Dupuytren's]
N48.6	Induration penis plastica (Peyronie's disease)

### References

1. U.S. Food and Drug Administration. Xiaflex. Last Revised: July, 2023.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/125338s111lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125338s111lbl.pdf)
2. Pess et al 2024: A consensus study on Collagenase Clostridium Histolyticum for Dupuytren Disease: A Delphi-Based Consensus Study. Journal of Hand Surgery Global Online, Volume 6, Issue 2, 2024, Pages 151-158, ISSN 2589-5141.  
<https://www.sciencedirect.com/science/article/pii/S2589514123001858>
3. Sandler AB, Scanaliato JP, Dennis T, Gonzalez Trevizo GA, Raiciulescu S, Nesti L, Dunn JC. Treatment of Dupuytren's Contracture With Collagenase: A Systematic Review. Hand (N Y). 2022 Sep;17(5):815-824. doi: 10.1177/1558944720974119. Epub 2021 Jan 21. PMID: 33478271; PMCID: PMC9465774.  
<https://pubmed.ncbi.nlm.nih.gov/33478271/>
4. Guo Y, Yang Y, Mao Q, Liu H, Wang T, Sun F, Wu J, Cui Y. Efficacy of collagenase Clostridium histolyticum combination therapies for Peyronie's disease: a systematic review and meta-analysis. Sex Med Rev. 2024 Jun 26;12(3):497-504. doi: 10.1093/sxmrev/qeae025. PMID: 38650382.  
<https://pubmed.ncbi.nlm.nih.gov/38650382/>

## **MP.097.MPC Xiaflex (Collagenase Clostridium Histolyticum)**

Policy Number: MP.097.MPC  
Last Review Date: 02/20/2025  
Effective Date: 03/01/2025

### **Disclaimer**

Maryland Physicians Care 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 Maryland Physicians Care 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.

Maryland Physicians Care 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 Maryland Physicians Care. Any sale, copying, or dissemination of said policies is prohibited.