

Premier Health Plan

POLICY AND PROCEDURE MANUAL

Policy Number: MP.097.PH
Last Review Date: 08/09/2018
Effective Date: 10/01/2018

MP.097.PH - Xiaflex (Collagenase Clostridium Histolyticum)

This policy applies to the following lines of business:

- ✓ Premier Employee

Premier Health Plan 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
- 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
- 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 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.

MP.097.PH - Xiaflex (Collagenase Clostridium Histolyticum)

Policy Number: MP.097.PH

Last Review Date: 08/09/2018

Effective Date: 10/01/2018

- 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.

Background

The American Academy of Orthopedic Surgeons defines Dupuytren's Contracture as the thickening of fibrous tissue layer underneath the skin of the palm and fingers. This contracture of fibrous tissue can cause the fingers to curl. It is more common in men than women and often runs in families.

The Urology Care Foundation defines Peyronie's Disease as a disease in which the plaques or segments of flat scar tissue form under the skin of the penis, causing the penis to bend or become indented during erections.

XIAFLEX is a prescription medicine used to treat adults with Dupuytren's contracture when a "cord" can be felt. It is also a prescription medicine used to treat adult men with Peyronie's disease who have a "plaque" that can be felt and a curve in their penis greater than 30 degrees when treatment is started. It is not known if XIAFLEX is safe and effective in children under the age of 18.

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)

MP.097.PH - Xiaflex (Collagenase Clostridium Histolyticum)

Policy Number: MP.097.PH
Last Review Date: 08/09/2018
Effective Date: 10/01/2018

References

1. American Academy of Orthopedic Surgeons. Dupuytren's Contracture. Last reviewed June 2017. <http://orthoinfo.aaos.org/topic.cfm?topic=a00008>
2. Auxilium Pharmaceuticals. XIAFLEX® – Full Prescribing Information. PL-1109-001.F. Rev. 70/2017. http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex_prescribing_information.html
3. Benhaim P. Treatment of Dupuytren's Disease. Hand Surgery Quarterly. Winter 2011: 6-17. <http://handsurgery.org/multimedia/files/newsletters/AAHS-Newsletter-Winter-2011.pdf>
4. Egui Rojo MA, Moncada Iribarren I, Carballido Rodriguez J, et al. Experience in the use of collagenase clostridium histolyticum in the management of Peyronie's disease: current data and future prospects. Ther Adv Urol. 2014 Oct;6(5):192-197. doi: 10.1177/1756287214537331. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4144260/>
5. Hay DC, Louie DL, Earp BE, et al. Surgical findings in the treatment of Dupuytren's disease after initial treatment with clostridial collagenase (Xiaflex). J Hand Surg Eur 2013 May 6;39(5):463-465. <http://jhs.sagepub.com/content/39/5/463.full.pdf+html>
6. Hayes Health Technology Brief. Xiaflex (collagenase Clostridium histolyticum) (Auxilium Pharmaceuticals Inc.) for Dupuytren Contracture. Publication date March 26, 2015.
7. Hayes Summary. Xiaflex (Auxilium Pharmaceuticals Inc.) for the Treatment of Peyronie's Disease. April 10, 2014.
8. Kirkpatrick DK. New treatments for Dupuytren's contracture. AAOS Now. October 2010 Issue. http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/news/aaosnow/oct10/clinical2.asp
9. Langston JP, Carson CC 3rd. Peyronie's disease: review and recent advances. Maturitas. 2014 Aug;78(4):341-3. doi: 10.1016/j.maturitas.2014.05.024. Epub 2014 Jun 6. <http://www.ncbi.nlm.nih.gov/pubmed/24984940>
10. Levine LA, Cuzin B, Mark S, et al. Clinical safety and effectiveness of collagenase clostridium histolyticum injection in patients with Peyronie's Disease: a Phase 3 open-label study. J Sex Med. 2014 Nov 12. doi: 10.1111/jsm.12731. [Epub ahead of print]. <http://www.ncbi.nlm.nih.gov/pubmed/25388099>
11. Peimer CA, McGoldrick CA, Fiore GC. Nonsurgical treatment of Dupuytren's contracture: 1-year US post-marketing safety data for collagenase clostridium histolyticum. Hand (NY) 2012 Jun;7(2):143-146. doi: 10.1007/s11552-012-9407-3. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351506/>

MP.097.PH - Xiaflex (Collagenase Clostridium Histolyticum)

Policy Number: MP.097.PH
Last Review Date: 08/09/2018
Effective Date: 10/01/2018

12. Peimer CA, Wilbrand S, Gerber RA, et al. Safety and tolerability of collagenase Clostridium histolyticum and fasciectomy for Dupuytren's contracture. J Hand Surg Eur Vol. 2014 Apr 29. [Epub ahead of print].
<http://jhs.sagepub.com/content/early/2014/04/29/1753193414528843.long>
13. Schulze SM, Tursi JP. Postapproval clinical experience in the treatment of Dupuytren's contracture with collagenase clostridium histolyticum (CCH): the first 1,000 days. Hand (N Y). 2014 Dec;9(4):447-458.
<http://www.ncbi.nlm.nih.gov/pubmed/25414604>
14. Sherer BA, Warrior K, Levine LA. 2013-2014 Updates in Peyronie's disease management. Curr Urol Rep. 2014 Dec;15(12):459. doi: 10.1007/s11934-014-0459-5. <http://link.springer.com/article/10.1007%2Fs11934-014-0459-5>
15. Urology Care Foundation. What is Peyronie's Disease? 2015.
<http://www.urologyhealth.org/urologic-conditions/peyronies-disease>
16. U.S. Food and Drug Administration (FDA). Biologics License Application 125338/0. BLA Approval: February 2, 2010. (Applicant: Auxilium Pharmaceuticals, Inc.).
http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/125338s000ltr.pdf
17. U.S. Food and Drug Administration (FDA). News Release: Issued Dec. 6, 2013. FDA approves first drug treatment for Peyronie's disease.
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm377849.htm>

Disclaimer:

Premier Health Plan 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 Premier Health Plan 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.

Premier Health Plan 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 Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.