

# Xiaflex (collagenase clostridium histolyticum)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Dosing Limits per Indication
Xiaflex (collagenase clostridium histolyticum)	<p><b>Dupuytren's Contracture</b> Up to 2.32 mg per 28 days. Lifetime Maximum: 3 injections per affected cord</p> <p><b>Peyronie's Curvature</b> 1.16 mg per 7 days. Lifetime Maximum: 8 injections per Peyronie's plaque</p>

## **APPROVAL CRITERIA**

Requests for injection of Xiaflex (collagenase clostridium histolyticum) may be approved for the following:

- I. Individual has a diagnosis of Dupuytren's contracture; **AND**
- II. Product will be injected into a palpable palmar cord that impairs the individual's functional activities; **AND**
- III. Documentation is provided that the palpable palmar cord measures either:
  - A. 20 degrees or more at the metacarpophalangeal joint; **OR**
  - B. 20 degrees or more at the proximal interphalangeal joint;

### **OR**

- IV. Individual has a diagnosis of Peyronie's disease; **AND**
- V. Disease is stable as defined by symptoms ( including but not limited to, penile curvature and pain) for at least 6 months (AUA); **AND**
- VI. Documentation is provided that penile curvature greater than or equal to 30 degrees and less than or equal to 90 degrees (AUA); **AND**
- VII. Individual has intact erectile function with or without use of medications (AUA); **AND**
- VIII. Documentation is provided that individual has palpable penile plaque(s).

Xiaflex (collagenase clostridium histolyticum) may not be approved for the following:

- I. Individual is using for cosmetic indications, including, but not limited to, the treatment of cellulite; **OR**
- II. Individual is using for Peyronie's plaques that involve the penile urethra; **OR**
- III. When the above criteria are not met and for all other indications.

**Note:**

Xiaflex has a black box warning for corporal rupture (penile fracture) or other serious penile injury when administered for the treatment of Peyronie's disease. Due to the risks of corporal rupture and other serious penile injury, Xiaflex is only available for the treatment of Peyronie's disease through a restricted REMS program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the Xiaflex REMS website: <http://www.xiaflexrems.com>.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 16, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. Nehra A, Alterowitz R, Culkin DJ, et al: American Urological Association Education and Research, Inc., Peyronie's Disease: AUA Guideline. J Urol. 2015; 194(3):745-753. Accessed: August 16, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.