

Policy Name	Policy Number	Scope								
Xiaflex (collagenase clostridium histolyticum) injection	MP-RX-FP-104-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth								
<p><b>Service Category</b></p> <table border="0"> <tr> <td><input type="checkbox"/> Anesthesia</td> <td><input type="checkbox"/> Medicine Services and Procedures</td> </tr> <tr> <td><input type="checkbox"/> Surgery</td> <td><input type="checkbox"/> Evaluation and Management Services</td> </tr> <tr> <td><input type="checkbox"/> Radiology Procedures</td> <td><input type="checkbox"/> DME/Prosthetics or Supplies</td> </tr> <tr> <td><input type="checkbox"/> Pathology and Laboratory Procedures</td> <td><input checked="" type="checkbox"/> Part B DRUG</td> </tr> </table>			<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Medicine Services and Procedures	<input type="checkbox"/> Surgery	<input type="checkbox"/> Evaluation and Management Services	<input type="checkbox"/> Radiology Procedures	<input type="checkbox"/> DME/Prosthetics or Supplies	<input type="checkbox"/> Pathology and Laboratory Procedures	<input checked="" type="checkbox"/> Part B DRUG
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<p><b>Service Description</b></p> <p>This document addresses the use of <a href="#">Xiaflex (collagenase clostridium histolyticum) injection</a> , a drug approved by the Food and Drug Administration (FDA) for the treatment of <a href="#">Dupuytren’s contracture and Peyronie’s disease</a>.</p> <p><b>Background Information</b></p> <p>This document addresses the use of Xiaflex (collagenase clostridium histolyticum) which is a biologic that hydrolyzes native collagen. When injected into fibrous cords, Xiaflex can lead to a reduction in contracture and improvement in range of motion of the affected joints. Xiaflex is approved for the treatment of Dupuytren’s contracture and Peyronie’s disease. Dupuytren’s disease is a progressive fibroproliferative disorder of an unknown origin affecting the hands causing permanent flexion contracture of the fingers. Surgery (fasciectomy) has been the mainstay treatment for Dupuytren’s. An alternative to invasive surgery is injection of collagenase to break up the fibrous cord responsible for the contracture.</p> <p>Peyronie’s disease is a connective tissue disorder which involves the growth of fibrous plaque in the soft tissue of the penis which can lead to symptoms such as penile curvature and pain. The 2015 American Urological Association (AUA) Peyronie’s Disease guidelines recommend intralesional Xiaflex in combination with modeling by the clinician and patient for the reduction of penile curvature in patients with stable Peyronie’s disease, penile curvature &gt;30° and &lt;90 , and intact erectile function (with or without the use of medications)</p> <p>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 restricted REMS program. Additional information and forms for individuals, prescribers and pharmacists may be found on the Xiaflex REMS website: <a href="http://www.Xiaflexrems.com">http://www.Xiaflexrems.com</a>.</p>										

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<b>Approved Indications</b> <ul style="list-style-type: none"> <li>A. Dupuytren’s contracture</li> <li>B. Peyronie’s disease</li> </ul>								
<b>Applicable Codes</b> <p>The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.</p>								
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<p><b>Medical Necessity Guidelines</b></p> <p>When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.</p> <p><i>Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.</i></p> <p>Xiaflex (collagenase clostridium histolyticum) injection</p> <p><b>A. Criteria For Initial Approval</b></p> <p>Requests for injection of Xiaflex (collagenase clostridium histolyticum) may be approved for the following:</p> <ul style="list-style-type: none"> <li>I. Individual has a diagnosis of Dupuytren’s contracture; AND</li> <li>II. Documentation is provided that product will be injected into a palpable palmar cord that impairs the individual’s functional activities; AND</li> <li>III. Documentation is provided that the palpable 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</li> <li>V. Disease is stable as defined by symptoms (such as, but not limited to penile curvature and pain) for at least 6 months (AUA); AND</li> <li>VI. Documentation is provided that penile curvature is greater than or equal to 30 degrees and less than or equal to 90 degrees (AUA); AND</li> <li>VII. Individual has intact erectile function with or without the use of medications (AUA); AND VIII. Documentation is provided that individual has palpable penile plaque(s)</li> </ul> <p><b>B. Authorization Duration</b></p> <ul style="list-style-type: none"> <li>i. Dupuytren’s contracture             <ul style="list-style-type: none"> <li>a. Initial Approval Duration: 6 months</li> <li>b. Reauthorization Approval Duration: 6 months to complete a treatment course</li> </ul> </li> <li>ii. Peyronie’s disease             <ul style="list-style-type: none"> <li>a. Initial Approval Duration: 12 months</li> <li>b. Reauthorization Approval Duration: 12 months to complete a treatment course</li> </ul> </li> </ul>		

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## Limits or Restrictions

### A. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

Drug	Limit
Xiaflex (collagenase clostridium histolyticum) 0.9mg vial	Dupuytren’s Contracture: up to 2.32 mg per 28 days Lifetime Maximum: 3 injections per affected cord  Peyronie’s Curvature: 1.16 mg per 7 days Lifetime Maximum: 8 injections per Peyronie’s plaque

## Reference Information

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 polices may take precedence over the application of this clinical criteria.

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# Medical Policy

Healthcare Services Department

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<b>Policy History</b>			
<b>Revision Type</b>	<b>Summary of Changes</b>	<b>P&amp;T Approval Date</b>	<b>MPCC Approval Date</b>
Policy Inception	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023
Revised: 9/27/23			