



MEDICAL COVERAGE GUIDELINES  
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 12/13/16  
LAST REVIEW DATE: 01/22/19  
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## PEYRONIE'S DISEASE TREATMENTS

- Extracorporeal Shock Wave Therapy (ESWT)
- Iontophoresis
- Nesbit Plication
- Plaque Incision with Graft

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **PEYRONIE'S DISEASE TREATMENTS (cont.)**

### **Description:**

Peyronie's disease is an acquired inflammatory disease of the tunica albuginea and adjacent erectile tissue of the penis. It most commonly affects men between the ages of 45 and 60. In the acute inflammatory stage, the individual may experience pain during flaccidity and/or during erection or sexual intercourse. The pain usually resolves over several months as the acute inflammation subsides, and the condition evolves to a progressive fibrosis with development of a palpable plaque. The plaque may result in curvature of the penis, erectile dysfunction or distal flaccidity. In some individuals, the plaque may resolve and disappear entirely. The etiology of Peyronie's is unknown, but is thought to be related to subclinical trauma.

Treatments for Peyronie's Disease include, *but are not limited to:*

- Extracorporeal Shock Wave Therapy (ESWT)
- Implantable Penile Prosthesis
- Iontophoresis
- Nesbit plication for Peyronie's disease
- Plaque incision with graft for Peyronie's disease
- Xiaflex (collagenase clostridium histolyticum)

### **Extracorporeal Shock Wave Therapy (ESWT):**

A noninvasive procedure that has been investigated for the treatment of Peyronie's disease. It is the process of applying low or high energy intensity shock or sound waves to a targeted site.

### **Iontophoresis:**

The transdermal delivery of a substance bearing a charge through the skin by a low electrical current. Iontophoresis has been investigated as a treatment for Peyronie's disease.

### **Nesbit Plication for Peyronie's Disease:**

Tissue on the unaffected side of the penis is shortened, canceling the bending effect.

### **Plaque Incision with Graft for Peyronie's Disease:**

Linear cuts are made in the plaque and then covered with grafted material, lengthening the curved side of the penis.



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## PEYRONIE'S DISEASE TREATMENTS (cont.)

### Description: (cont.)

#### Sexual Dysfunction:

The continual impairment of customary patterns of sexual interest and/or responses of an individual or a couple. Sexual dysfunction may result from organic diseases or conditions (e.g., Peyronie's disease, severe diabetes, vascular disease), trauma or surgery or it may be non-organic in nature (e.g., psychogenic).

In males, lack of sexual arousal is evidenced by erectile dysfunction, also called impotence. Erectile dysfunction is the inability to consistently attain or sustain erection adequate for sexual penetration.

#### Xiaflex (collagenase clostridium histolyticum):

A biologic agent that enzymatically disrupts collagen and has been used as a non-surgical alternative for the treatment of fibroproliferative disorders such as Dupuytren's contracture and Peyronie's disease.

### Definitions:

#### Risk Evaluation and Mitigation Strategies (REMS):

Use of Xiaflex is subject to a Risk Evaluation and Mitigation Strategies (REMS) program that requires provider, patient, and dispensing pharmacy be enrolled into the program. Only providers and Pharmacies enrolled into the REMS may prescribe and dispense the drug, respectively, to individuals who are also in the program. A REMS program attempts to manage known or potentially serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some drugs to ensure that the benefits of a drug outweigh its risks.

Adult: Age 18 years and older



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## PEYRONIE'S DISEASE TREATMENTS (cont.)

### Criteria:

For Extracorporeal Shock Wave Therapy (ESWT) for plantar fasciitis, see BCBSAZ Medical Coverage Guideline #O589, "*Foot Disorder Treatments*".

For treatment of Peyronie's Disease with implantable penile prosthesis, see BCBSAZ Medical Coverage Guideline #O727, "*Erectile Dysfunction Treatments*".

For Xiaflex for all other indications,-refer to eviCore.

**COVERAGE FOR TREATMENT OF PEYRONIE'S DISEASE IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.**

If benefit coverage for sexual dysfunction is available, requests for treatment for sexual dysfunction will be reviewed by the medical director(s) and/or clinical advisor(s).

### Nesbit Plication or Plaque Incision with Graft:

- If benefit coverage for sexual dysfunction is available, Nesbit plication or plaque incision with graft for treatment of Peyronie's disease is considered **medically necessary**.

### Extracorporeal Shock Wave Therapy (ESWT):

- If benefit coverage for sexual dysfunction is available, extracorporeal shock wave therapy for treatment of Peyronie's disease is considered **experimental or investigational** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

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## PEYRONIE'S DISEASE TREATMENTS (cont.)

Criteria: (cont.)

Iontophoresis:

- **If benefit coverage for sexual dysfunction is available**, iontophoresis for treatment of Peyronie's disease is considered *experimental or investigational* based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

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Resources:

Literature reviewed 02/01/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 04/16/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.01.62 BCBS Association Medical Policy Reference Manual. Extracorporeal Shock Wave Therapy in the Treatment of Peyronie's Disease. Re-issue date 07/09/2009, issue date 10/09/2003.
2. 5.01.19 BCBS Association Medical Policy Reference Manual. Injectable Clostridial Collagenase for Fibroproliferative Disorders. Re-issue date 12/14/2017, issue date 03/11/2010.
3. Chung E. Peyronie's disease and low intensity shock wave therapy: Clinical outcomes and patient satisfaction rate in an open-label single arm prospective study in Australian men. *Korean journal of urology*. Nov 2015;56(11):775-780.
4. Fojecki GL, Tiessen S, Osther PJ. Extracorporeal shock wave therapy (ESWT) in urology: a systematic review of outcome in Peyronie's disease, erectile dysfunction and chronic pelvic pain. *World journal of urology*. Apr 23 2016.



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## PEYRONIE'S DISEASE TREATMENTS (cont.)

### Resources: (cont.)

5. Gao L, Qian S, Tang Z, Li J, Yuan J. A meta-analysis of extracorporeal shock wave therapy for Peyronie's disease. *International journal of impotence research*. Sep 2016;28(5):161-166.
6. Guillot-Tantay C, Phe V, Chartier-Kastler E, Mozer P, Bitker MO, Roupret M. [Medical and surgical treatments of congenital and acquired penile curvatures: a review]. *Prog Urol*. Mar 2014;24(3):203-211.
7. Hatzimouratidis K, Eardley I, Giuliano F, et al. EAU guidelines on penile curvature. *European urology*. Sep 2012;62(3):543-552.
8. Jordan GH, Carson CC, Lipshultz LI. Minimally invasive treatment of Peyronie's disease: evidence-based progress. *BJU Int*. Jul 2014;114(1):16-24.
9. Kokab A, Wylie K, Allen P, Shetty A, Davies-South D. Structured Self-Rated Response to Iontophoresis with Verapamil and Dexamethasone in Peyronie's Disease. *Adv Urol*. 2014;2014:957013.
10. Paulis G, Brancato T. Inflammatory mechanisms and oxidative stress in Peyronie's disease: therapeutic "rationale" and related emerging treatment strategies. *Inflamm Allergy Drug Targets*. Feb 2012;11(1):48-57.
11. UpToDate. Peyronie's disease: Diagnosis and medical management. 08/18/2017, 05/26/2016.



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**PEYRONIE’S DISEASE TREATMENTS (cont.)**

**Resources:** (cont.)

Xiaflex Package Insert:

- FDA-approved indication and dosage:

Indication	Recommended Dose
<p>Adult men with Peyronie’s disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy</p>	<p>The dose of Xiaflex is 0.58 mg per injection administered into a Peyronie’s plaque. If more than one plaque is present, inject into the plaque causing the curvature deformity.</p> <p>A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of two Xiaflex injection procedures and one penile modeling procedure. The second Xiaflex injection procedure is performed 1 to 3 days after the first. The penile modeling procedure is performed 1 to 3 days after the second injection of the treatment cycle. The interval between treatment cycles is approximately six weeks. The treatment course consists of a maximum of 8 injection procedures and 4 modeling procedures.</p> <p>If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or it is determined that further treatment is not clinically indicated, then the subsequent treatment cycles should not be administered.</p> <p>The safety of more than one treatment course of Xiaflex is not known.</p> <p>Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie’s disease, Xiaflex is available only through the XIAFLEX REMS Program. Required components of the program include the following:</p> <ol style="list-style-type: none"> <li>1. Prescribers must be certified with the program by enrolling and completing training in the administration of Xiaflex treatment for Peyronie’s disease.</li> <li>2. Healthcare sites must be certified with the program and ensure that Xiaflex is only dispensed for use by certified prescribers.</li> </ol>

**Approval for Peyronie’s Disease:**

Maximum of three (3) injections per plaque causing curvature deformity. The maximum dose per treatment is 0.58mg.

Repeat dosage: None



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'iditkidgo éí doodago Háida bíjá anilyeedigií t'áadoo le'é yina'iditkidgo beehaz'áanii hólo dií t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodiilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

### Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



