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MEDICAL COVERAGE GUIDELINES

SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: LAST REVIEW DATE: LAST CRITERIA REVISION DATE: ARCHIVE DATE: 04/16/13 04/01/14 03/05/14

PEYRONIE'S DISEASE TREATMENTS

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

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.

The section identified as "<u>Description</u>" 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 "<u>Criteria</u>" 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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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.

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PEYRONIE'S DISEASE TREATMENTS (cont.)

Description: (cont.)

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.

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.

Treatments for Peyronie's Disease include:

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

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PEYRONIE'S DISEASE TREATMENTS (cont.)

Criteria:

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).

If benefit coverage for sexual dysfunction is available, unless otherwise stated in the member's specific benefit booklet, coverage is only available for sexual dysfunction caused by or related to an organic disease or condition.

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

For treatment of Peyronie's disease with Xiaflex, see BCBSAZ Medical Coverage Guideline, "Xiaflex".

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,
 - 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:
 - 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.

Resources:

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. Hatzimouratidis K, Eardley I, Giuliano F, et al. EAU guidelines on penile curvature. *Eur Urol.* Sep 2012;62(3):543-552.
- 3. 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.

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