

Corporate Medical Policy

Penile Prosthesis “NOTIFICATION”

File Name: penile_prosthesis
Origination: 10/2024
Last Review: 10/2024

Policy Effective 1/1/2025

Description of Procedure or Service

Erectile dysfunction (ED) is defined as the inability to achieve and/or maintain penile erection sufficient for satisfactory sexual performance. Erectile dysfunction (ED) may result from systemic disorders such as hypertension, ischemic heart disease, diabetes mellitus and its prevalence increases with age.

Options for treatment include devices, medications or surgical procedures. Surgical implantation of a penile prosthesis is a treatment option for those with ED who have failed less invasive treatments. There are two types of implantable prostheses: semi-rigid and inflatable. Semi-rigid rods are implanted into the corpora cavernosa of the penis to provide rigidity. Inflatable cylinders are implanted in the penis and are connected to a fluid filled reservoir implanted in the abdomen, and a subcutaneous manual pump is implanted in the scrotum. When the cylinders are filled with fluid, penile rigidity is achieved.

Note: For penile prostheses related to gender affirmation surgery, please see medical policy titled Gender Affirmation Surgery.

Related Policies:

Gender Affirmation Surgery

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Penile Prosthesis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Please see the following section “Benefits Application” regarding specific benefit coverage/exclusions.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

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Penile Prosthesis may be specifically excluded under some health benefit plans. Please refer to the Member’s Benefit Booklet for availability of benefits.

When Penile Prosthesis is covered

- I. Following a comprehensive history and physical exam that includes appropriate laboratory testing, a surgically implanted penile prosthesis may be considered medically necessary for treatment of erectile dysfunction when **all** the following criteria are met:
 - A. Erectile dysfunction has been present for at least 6 months **AND**
 - B. Erectile dysfunction is due to one or more of the following:
 - Neurologic condition (e.g., diabetic neuropathy, multiple sclerosis, spina bifida)
 - Vascular condition (e.g., hypertension, intrapenile arterial disease)
 - Pelvic trauma with urinary system injury
 - Previous radiation therapy to the pelvis
 - Spinal cord injury/disease
 - Complication of surgery (e.g., cystectomy, prostatectomy) **AND**
 - C. Individual does not have psychogenic erectile dysfunction, untreated depression or untreated psychiatric illness **AND**
 - D. One or more of the following medical therapies have been tried and failed or individual has contraindications to all the following:
 - Oral medications (i.e., phosphodiesterase-5 [PDE5] inhibitors);
 - Vacuum constriction device;
 - Intracavernosal injection;
 - Intraurethral medications. **AND**
 - E. Individual is free of contraindications including but not limited to:
 - Systemic infection
 - Active urogenital infection or
 - Active skin infection in the region of surgery. **AND**
 - F. Individual has never smoked OR has abstained from smoking, use of smokeless tobacco and/or nicotine products, and/or nicotine replacement therapy for at least 6 weeks prior to surgery.
- II. Removal of an implanted penile prosthesis may be considered medically necessary for any of the following:
 - infection; or
 - mechanical failure; or
 - urinary obstruction; or
 - intractable pain.

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- III. Replacement of an implanted penile prosthesis may be considered medically necessary when the medical necessity criteria in section I continue to be met.

When Penile Prosthesis is not covered

Implantation, removal and/or replacement of a penile prosthesis is considered not medically necessary when the criteria above are not met.

Policy Guidelines

A penile prosthesis may be surgically implanted when non-surgical therapies have been proven to be ineffective. This procedure precludes any future pharmacological treatment as surgery destroys the corpus cavernosum of the penis.

Potential risks and complications of penile prostheses include erosion of the device, mechanical failure and the possibility of infection, device extrusion, migration, urinary obstruction and prolonged or intractable pain. Individuals with diabetes, spinal cord injuries or urinary tract infections have an increased risk of prosthesis-associated infections. It may be necessary to remove the prosthesis if the infections cannot be successfully treated with antibiotics. After an infected prosthesis is removed, replacement with a new prosthesis should be delayed allowing adequate healing and eradication of infection.

In 2018, the AUA published an updated guideline on ED. Recommendations in this guideline that are specific to penile prosthesis implantation are as follows:

- Men with ED should be informed regarding the treatment option of penile prosthesis implantation, including discussion of benefits and risks/burdens. (Strong Recommendation; Evidence Level: Grade C)
- Men with ED who have decided on penile implantation surgery should be counseled regarding post-operative expectations. (Clinical Principle)
- Penile prosthetic surgery should not be performed in the presence of systemic, cutaneous, or urinary tract infection. (Clinical Principle)

The guideline stated, “the potential risks and burdens of prosthesis surgery include the risks inherent in the surgical procedure, possible changes in the appearance of the penis, and the potential for device malfunction or failure”.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbssc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, C1813, C2622

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Burnett AL, Nehra A, Breau RH, Culkin DJ, Faraday MM, Hakim LS, et al. Erectile Dysfunction: American Urological Association Guideline. J Urol. 2018; 200(3):633.

Impotence. NIH Consensus Statement 1992; 10: 1.

McCabe MP, Sharlip ID, Atalla E et al: Definitions of sexual dysfunctions in women and men: a consensus statement from the Fourth International Consultation on Sexual Medicine 2015. J Sex Med 2016; 13: 135. PMID: 26953828

United States Food and Drug Administration (FDA). Code of Federal Regulations Title 21, Subpart D-- Sec. 876.3350 Penile inflatable implant. May 24, 2023. Retrieved October 3, 2024 <https://www.ecfr.gov/current/title-21/chapter-I/subchapterH/part-876/subpart-D/section-876.3350>

United States Food and Drug Administration (FDA). Class II special controls guidance document: external penile rigidity devices. Dec 28, 2004. Page last updated Jun 29, 2018. Retrieved October 3, 2024 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072098.htm>

Trost L, Wanzek P, Bailey G. A practical overview of considerations for penile prosthesis placement. Nat Rev Urol. 2016; 13(1):33-46. PMID: 26620609

Morales A. Erectile dysfunction: an overview. Clin Geriatr Med. 2003 Aug;19(3):529-38.

Hellstrom WJG. Penile prosthesis implantation. Updated June 2022. Retrieved October 3, 2024 from <https://emedicine.medscape.com/article/446761-overview>

Policy Implementation/Update Information

10/30/24 New policy developed. BCBSNC will provide coverage for Penile Prosthesis when it is determined to be medically necessary because the medical criteria and guidelines listed within the policy are met. Medical Director review 10/2024. **Notification given on 10/30/2024 for effective date 1/1/2025.** (tm)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.