Anthem

Clinical UM Guideline

Subject: Penile Prosthesis Implantation
Guideline #: CG-SURG-12
Status: Revised

Publish Date: 06/28/2023
Last Review Date: 05/11/2023

Description

This document addresses the criteria for implantation of a penile prosthesis, which is an established technique for treating erectile dysfunction (ED).

Note: This document does not address gender affirming surgery or procedures. Criteria for gender affirming surgery or procedures are found in applicable guidelines used by the plan.

Clinical Indications

Medically Necessary:

The implantation of a penile prosthesis is considered **medically necessary** for individuals who meet the following criteria:

A. Have erectile dysfunction of greater than 6 months duration; **and**
B. Experienced failure of or have contraindication to less invasive treatments including one or more of the following:
    1. Oral medication; **or**
    2. Intracavernosal injection; **or**
    3. Vacuum constriction device.

The implantation of a replacement penile prosthesis is considered **medically necessary** for individuals who meet the following criteria:

A. The individual is likely to obtain continued benefit derived from use of the device; **and**
B. One of the following:
    1. The device experienced mechanical failure; **or**
    2. The individual has a medical indication for device removal.

Not Medically Necessary:

The implantation of a penile prosthesis is considered **not medically necessary** when the above criteria are not met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
HCPCS	
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
L8699	Prosthetic implant, not otherwise specified
ICD-10 Procedure	
0VUS0JZ	Supplement penis with synthetic substitute, open approach
0VUS4JZ	Supplement penis with synthetic substitute, percutaneous endoscopic approach
ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

Discussion/General Information

The American Urological Association's (AUA) 2018 erectile dysfunction (ED) guideline defines ED as "…the consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual satisfaction, including satisfactory sexual performance."

According to the AUA guideline, independent risk factors for ED are similar to those for cardiovascular disease. These include, among others, smoking, diabetes mellitus, hypertension, dyslipidemia and obesity. Between 20% and 85% of men with diabetes, and approximately 35% of men with dyslipidemia, experience ED (AUA, 2018). Moreover, approximately 75% of men with heart failure experience ED, and causes of ED in men with heart failure include arterial insufficiency, endothelial dysfunction, reduced cardiac capacity and side effects of medication for cardiovascular disease (Rastogi, 2005). In addition, surgery (especially radical prostate and bladder surgery for cancer) and radiotherapy can injure nerves and arteries near the penis, causing ED (Chung, 2014). Injury to the penis, spinal cord, prostate, bladder, and pelvis can lead to ED by harming nerves, smooth muscles, arteries, and fibrous tissues of the corpora cavernosa.

Penile prosthesis implantation is a treatment option for men with ED who have failed less invasive treatments. For those without other comorbidities, oral phosphodiesterase-5 (PDE5) inhibitors such as sildenafil and tadalafil are usually first-line therapies, unless contraindicated. Recent meta-analyses have found that all available oral PDE5 inhibitors are effective, compared with placebo, with similar efficacy of the various PDE5 inhibitors (Allen, 2019). For men with testosterone deficiency, PDE5 inhibitors can be supplemented with testosterone therapy (AUA, 2018). If oral medications are not sufficient, a vacuum device, which is a noninvasive modality, is often recommended before a penile prosthesis. Underlying causes for erectile dysfunction are important to identify and address, if possible, with appropriate interventions.

The U.S. Food and Drug Administration (FDA) considers the rigid penile implant as a Class II device. The semi-rigid rods are implanted into the corpora cavernosa of the penis to provide rigidity. Inflatable penile implants are considered Class III devices by the FDA. Inflatable cylinders are implanted in the penis and are connected to a reservoir filled with fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. Penile rigidity is achieved when the cylinders are filled with fluid.

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".

In 2022, an international group of key opinion leaders and prosthetic surgeons published a consensus statement on penile prosthesis (Chung, 2022). The group did not represent a recognized specialty society. The statement included the following recommendations regarding criteria for penile implantation surgery:

> Clinical assessment and patient selection

- Penile prosthesis implantation is considered an appropriate treatment option for a man who is not achieving a satisfactory erection and wishes for a permanent solution for erectile dysfunction (Grade C).
- Proper patient selection, counselling and informed consent are essential, coupled with optimization of existing medical conditions especially diabetes (Grade B).
- Adequate prophylactic measures should be taken to minimize prosthetic infection and bleeding or thromboembolic risk to ensure good clinical outcomes (Grade B).

The document states:

> Known patient factors that increase the risk of prosthetic complications and lower satisfaction rates are those with diabetes mellitus, the presence of pathological nasal and skin flora (for example, Staphylococcus spp.), long-term steroid use, poor personal hygiene, suboptimal antimicrobial practice, poor cardiovascular status, history of radiation therapy, spinal cord injury, urinary catheterization, immunosuppression and concurrent genitalia reconstructive surgery. Optimization of these risk factors and adequate patient counselling are essential before surgery…
>
> Strong evidence suggests that high-risk patient populations, such as men with uncontrolled diabetes mellitus, corporal fibrosis (for example, PD or priapism) and those who are undergoing salvage penile implants are at a greater risk of prosthetic complications, especially device infection and erosion.

Penile prostheses have primarily been evaluated in uncontrolled case series. For example, Zermann and colleagues (2006) studied penile implant efficacy in 245 neurologically impaired men. Men were categorized into 3 groups based on the indication for penile prosthetic surgery. Group 1 consisted of 134 participants with urinary management only, Group 2 had 60 participants with erectile dysfunction only, and Group 3 had 51 participants with urinary management and erectile dysfunction. At a mean follow-up of 7.2 years (maximum 17 years), 195 participants were reevaluated in the clinic. Outcomes showed that in 122 participants (90.3%) urinary management problems were resolved, and erectile dysfunction treatment was successful in 76 participants (82.6%). A total of 43 revisions were performed for complications (e.g., infections and device perforation).

Sevinc and colleagues (2017) evaluated outcomes after penile prosthesis implantation in 181 men with ED of different etiologies. Primary causes of ED were diabetes in 81 men (44.7%), vascular disease in 45 men (25.4%), radical pelvic surgery in 29 men (16%) and a variety of other reasons in the remaining 25 men (13.8%). The most common post-operative complications were superficial wound infection (n=17, 9.4%), dehiscence of the glans penis (n=10, 5.5%), which resolved after 1 month, and pain during intercourse (n=10, 5.5%), which resolved within a few months. The mean time to first intercourse was 54 days (range: 9 to 150 days). Individuals were followed for at least 12 months. At follow-up, 104 individuals (57.5%) reported being very satisfied with the penile prosthesis, 48 (26.5%) were satisfied and 21 (11.6%) were not satisfied. A total of 21 prostheses (11.6%) were removed because of complications or patient dissatisfaction.

Khera and colleagues (2018) reported data from an industry-sponsored registry of individuals who were implanted with American Medical Systems (AMS) penile implants. A total of 1180 individuals with ED were included in the registry. Of these, 250 individuals (21.2%) had Peyronie's disease (PD). At 1- and 2-year follow-ups, 88.6% and 88.5%, respectively, of individuals with PD stated that they were either satisfied or very satisfied with treatment. The rate of self-reported depression in individuals with PD decreased from 19.3% at baseline to 10.5% at the 1-year follow-up (p=0.02).

Topuz (2021) reported on 128 individuals who underwent penile prosthesis implantation due to ED. Median follow-up was 16 years (range, 2 to 25 years). Complications were experienced by 42 (30%) of individuals. Thirteen (9%) individuals had a prosthesis infection; most of these (n=8) occurred in the first 3 months after implantation. Other complications included pain, wound infection and dysuria. A total of 27 (19.7%) individuals underwent salvage or revision surgery.

In terms of complication rates, Minervini and colleagues (2006) studied 447 men who had 504 penile prosthetics implanted and found that infection was the most frequent complication. Other complications were implant migration and tissue erosion. In a review by Phe (2012), the rate of infection decreased to 1% with the utilization of antibiotic impregnated implants. In a report on 98 men in a national database who had penile prosthesis implantation between 2005 and 2013 (Palma-Zamora, 2017), the overall 30-day complication rate was 11% (n=11). The complications included surgical site infection (n=6), transfusion (n=3), urinary tract infection (n=1) and sepsis/shock (n=1).

Carvajal and colleagues (2020) published a systematic review of studies on factors associated with infection in individuals with penile prostheses. They included 40 studies with a total of 175,592 individuals. Fifteen studies focused on diabetes mellitus which was found in pooled analyses to be significantly associated with risk of infection (odds ratio [OR], 2.48; 95% confidence interval [CI], 1.38 to 4.47). Other factors significantly increasing risk of infection in individuals with penile prostheses were immunosuppression (3 studies, OR, 20.99; 95% CI, 0.71 to 622.34) and obesity (2 studies, OR, 18.24; 95% CI, 1.43 to 231.98). However, other than in the analysis on diabetes mellitus, numbers of studies and total sample sizes were small and thus estimates of increased risk were imprecise as indicated by wide confidence intervals.

A 2020 systematic review by Dick and colleagues identified 14 studies reporting on outcomes after penile prosthesis implantation in individuals with solid organ transplant. Most of the studies were case reports or case series but there were also 2 retrospective cohort studies. Overall, the studies included 143 individuals with solid organ transplant and 191 controls without solid organ transplant, all of whom received penile prostheses. In a pooled analysis, the authors did not find a significant difference in the prosthetic infection rate among individuals with solid organ transplant (2.1%) and controls (3.7%), p=0.53. They also did not find a statistically significant difference in the rate of non-infective complications in individuals with solid organ transplant (9.8%) versus controls (4.7%), p=0.08. A limitation of the literature on this topic is that most studies were small and uncontrolled, and all were retrospective.

A systematic review of studies on penile prosthesis implantation in individuals with spinal cord injuries was published by Pang and colleagues in 2022. The authors identified 11 studies of adult men at least 18 years old with a diagnosis of ED secondary to spinal cord injury and who underwent penile prosthesis implantation. All of the studies were retrospective observational studies. The studies included a total of 1514 individuals, 475 931%) of which had spinal cord injuries. In individual studies, the complication rate was 4.2% to 61.1% in the spinal cord injury population. The explantation rate was 2.1% to 16.7%, and the revision/reimplant rate was 2.7% to 44.4%. Nine of the studies evaluated function after penile prosthesis implantation, but none used a validated questionnaire to assess the functional outcomes. The proportion of individuals who reported satisfaction with the penile implant used for sexual intercourse ranged from 79.2 to 92.9% and satisfactory sexual intercourse was reported in 35 to 86.1% of men. The authors did not pool study outcomes.

In 2015, Lleda-Garcia and colleagues published findings of a survey of 149 individuals who had received first (n=110) or replacement (n=39) inflatable penile prostheses at a single center. The most common reason for replacement of a device (n=30) was mechanical failure, followed by infection in 4 individuals, extrusion in 3 individuals and device intolerance in 2 individuals. The rates of satisfactory sexual intercourse after implantation were similar in individuals who had received first implants (79%) or replacement implants (80%). Satisfactory sexual intercourse was also reported by 74.1% of sexual partners after first implantation and 80% after replacement implantation.

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Surgeons National Surgical Quality Improvement Program-based evaluation. Trans Androl Urol. 2017; 6: S767-S773.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Association of Clinical Endocrinologists (AACE) Male Sexual Dysfunction Task Force. Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Male Sexual Dysfunction: A couple's problem. 2003. Available at https://pro.aace.com/disease-state-resources/reproductive-and-gonad/clinical-practice-guidelines/aace-medical-0. Accessed on February 17, 2023.
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Websites for Additional Information

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History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised hierarchy and formatting of Clinical Indications section. Revised criterion B in first medically necessary statement. Updated Discussion/General Information and References sections.
Revised	05/12/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Added medically necessary statement on replacement of penile prostheses. Discussion/General Information and References sections updated.
Revised	05/13/2021	MPTAC review. In Medically Necessary statement, changed "impotence" to "erectile dysfunction; changed required duration from 1 year to 6 months; and reformatted and simplified criteria. Discussion/General Information and References sections updated. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	06/06/2019	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date". Discussion/General information and References sections updated.
Reviewed	08/03/2017	MPTAC review. Updated formatting in the Position Statement section. Updated References section.
Reviewed	08/04/2016	MPTAC review. Updated Discussion/General Background, and References sections. Updated formatting in Position Statement section. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. Reformatted and reorganized criteria. Added medically necessary criteria for radiation therapy. Added pelvis and retroperitoneum to major surgery group. Updated Description, Discussion/General Background, and References sections.
Reviewed	11/13/2014	MPTAC review. Updated Description, Discussion/General Background, and References sections.
Reviewed	11/14/2013	MPTAC review. Updated Discussion/General Background, References and Websites sections.
Reviewed	11/08/2012	MPTAC review. Discussion and References updated.
Reviewed	11/17/2011	MPTAC review. Discussion, Coding and References updated.
Reviewed	11/18/2010	MPTAC review. Discussion and References updated.
Reviewed	11/19/2009	MPTAC review. Place of Service section deleted. Discussion and References updated.
Reviewed	11/20/2008	MPTAC review. References updated.
Reviewed	11/29/2007	MPTAC review. References and coding were updated.
Reviewed	12/07/2006	MPTAC review. References updated; no change to guideline criteria.
Revised	12/01/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title

Anthem, Inc.			No Document
Anthem BCBS			No Document
WellPoint Health Networks, Inc.	12/02/2004	Clinical Guideline	Penile Prosthesis Insertion

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.