Medical Policy:
Penile Implants

POLICY NUMBER	EFFECTIVE DATE	APPROVED BY
EH.CCI.SU.01	2/14/2025	MPC (Medical Policy Committee)

IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:

 The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies (LMRP). All coding and web site links are accurate at time of publication.

Overview

A penile prosthesis is a plastic device surgically implanted inside the penis in order to simulate an erection. There are two types of prostheses:

1. **Semi-rigid** (nonhydraulic): A semi-rigid but malleable rod. The semi-rigids are further divided into malleable and mechanical devices. Malleable prostheses are made of silicone rubber with an intertwined metallic core. Mechanical prostheses are also made of silicone rubber, with a column of interlocking rings that provide rigidity when they are lined up and flaccidity when the penis is bent.
2. **Inflatable** (hydraulic): A device that can be inflated with fluid to stiffen the penis. Inflatable prostheses may be comprised of 1, 2 or 3 pieces. The 1-piece device consists of a pair of hydraulic cylinders implanted within the corpora cavernosa. A pump at the distal end cycles fluid from a rear tip reservoir into a central chamber to produce penile rigidity.

Most devices will warrant replacement within 10 to 15 years. Surgical repair, removal or replacement of the prosthesis may also become necessary due to malfunction or patient complications.

Guideline

Penile implants are considered medically necessary for members ≥ 18 years of age when any of the following are documented as causal to erectile dysfunction:

- Failure or contraindication of alternative therapy (e.g., PDE-V inhibitors, vacuum devices or intracavernous injections)
- History of prostate, bladder, bowel or spinal surgery (e.g., cystectomy, prostatectomy, partial penectomy, abdominal-perineal resection, anterior exenteration or pelvic exenteration)
- Injury to genitalia or perineum
- Neurologic disease (e.g., diabetic neuropathy)
- Paraplegia or quadriplegia
- Pelvic radiation
- Pelvic trauma with urinary system injury
- Peyronie's disease
- Renal failure
- Vascular insufficiency or venous incompetence (venous leak)
- Vascular surgery with aorta or femoral vessel involvement
- Members with gender dysphoria in association with gender affirming surgery

For coverage of organic conditions that are not listed above, documentation must indicate all other failed treatment modalities. Circumcision may be indicated for patients with phimosis and balanitis. Implants may not be appropriate for patients with severe penile corporal fibrosis or severe medical illness.

Limitations/Exclusions

Penile implantation is not covered in the documented presence of any of the following:

- Psychogenic erectile dysfunction, which may be manifested as follows:
  - Inhibited sexual excitement
  - Inhibited orgasm
  - Premature ejaculation
  - Functional dyspareunia
- Alcohol or substance abuse.
- Any untreated medical condition

Procedure Codes

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
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
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 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

Diagnosis Codes

All diagnoses

References

Burnett AL. Evaluation and Management of Erectile Dysfunction. In Campbell-Walsh's Urology, 10th edition. Philadelphia: WB Saunders, Chapter 24, 2011.

AUA Guidelines: Erectile Dysfunction.

http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/edmgmt/chapter1.pdf

Porst H, Burnett A, Brock G, Ghanem H, Giuliano F, Glina S, Hellstrom W, Martin-Morales A, Salonia A, Sharlip I; ISSM Standards Committee for Sexual Medicine. SOP conservative (medical and mechanical) treatment of erectile dysfunction. J Sex Med. 2013 Jan;10(1):130-71.

Specialty matched clinical peer review.

Revision History

Company(ies)	DATE	REVISION
ConnectiCare	Feb 14, 2025	Transferred policy content to individual company branded template
EmblemHealth ConnectiCare	Feb. 11, 2022 Feb. 11, 2022	Reinstated New Policy