

Penile Prosthesis Surgery, Surgical 23

Table of Content

Purpose

Description & Definitions

Criteria

Coding

Document History

References

Special Notes

Keywords

Effective Date 6/1992

Next Review Date 7/2025

Coverage Policy Surgical 23

<u>Version</u> 5

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity of Penile Prosthesis Surgery.

Description & Definitions:

Penile Prosthesis is a surgical procedure to implant a device (semi rigid or inflatable) in the penis.

Criteria:

Penile Prosthesis is considered medically necessary for 1 or more of the following:

- Implantation of semi-rigid penile prosthesis or inflatable penile prosthesis (implantable penile pumps) for individuals who have documented physiologic erectile dysfunction with **All** of the following:
 - Absence of All of the following:
 - Untreated depression or psychiatric illness
 - Drug-induced impotence related to 1 or more of the following:
 - Alcohol
 - Anabolic steroids
 - Anticholinergics
 - Antidepressants
 - Antipsychotics
 - Central nervous system depressants
 - Illicit drug abuse
 - Normal levels of All of the following:
 - Prolactin
 - Testosterone
 - Thyroid hormone levels
 - History of 1 or more of the following:
 - Injury to the bladder, perineum/genitalia, and/or erection control

Surgical 23 Page 1 of 5

- Prior history of 1 or more of the following:
 - Prostate Surgery
 - Bladder Surgery
 - Bowel surgery
 - Spinal surgery
- Prior vascular surgery involving 1 or more of the following:
 - Aorta
 - Femoral blood vessels
- Neurological disease (e.g. diabetic neuropathy, spinal cord injury)
- Peyronie's disease
- Renal failure
- Vascular insufficiency documented by dynamic infusion cavernosometry and cavernosography (DICC)
- Venous incompetence documented by dynamic infusion cavernosometry and cavernosography (DICC)
- Venous leak of the penis
- Nonsurgical methods have been ineffective
- Removal of a penile implant is considered medically necessary for **1 or mo**re of the following:
 - o Intractable pain
 - Mechanical failure
 - Urinary obstruction
 - An infected prosthesis
- Reimplantation of a penile implant is considered medically necessary for individuals with All of the following:
 - Absence of All of the following:
 - Untreated depression or psychiatric illness
 - Drug-induced impotence related to 1 or more of the following:
 - Alcohol
 - Anabolic steroids
 - Anticholinergics
 - Antidepressants
 - Antipsychotics
 - Central nervous system depressants
 - Illicit drug abuse
 - Normal levels of all of the following:
 - Prolactin
 - Testosterone
 - Thyroid hormone levels
 - History of 1 or more of the following:
 - Injury to the bladder, perineum/genitalia, and/or erection control
 - Prior history of 1 or more of the following:
 - Prostate Surgery
 - Bladder Surgery
 - Bowel surgery
 - Spinal surgery
 - Prior vascular surgery involving 1 or more of the following:
 - Aorta
 - Femoral blood vessels
 - Neurological disease (e.g. diabetic neuropathy, spinal cord injury)
 - Peyronie's disease
 - Renal failure

Surgical 23 Page 2 of 5

- Vascular insufficiency documented by dynamic infusion cavernosometry and cavernosography (DICC)
- Venous incompetence documented by dynamic infusion cavernosometry and cavernosography (DICC)
- Venous leak of the penis
- o Nonsurgical methods have been ineffective
- Prior prosthesis was removed for medically necessary indications of 1 or more of the following:
 - o Intractable pain
 - o Mechanical failure
 - Urinary obstruction
 - o An infected prosthesis

Penile Prosthesis is considered not medically necessary for uses other than those listed in the clinical criteria.

Coding:

Medically necessary with criteria:

Coding	Description
CPT 54400	Insertion of penile prosthesis; non inflatable (semi-rigid)
CPT 54401	Insertion of penile prosthesis; inflatable (self-contained)
CPT 54405	Insertion of multi component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
CPT 54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
CPT 54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
CPT 54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
CPT 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
CPT 54415	Removal of non-inflatable (semi rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
CPT 54416	Removal and replacement of non-inflatable (semi rigid) or inflatable (self-contained) penile prosthesis at the same operative session
CPT 54417	Removal and replacement of non-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

• 2019: November

• 2008: June (remain archived)

Surgical 23 Page 3 of 5

- 2002: November (archived)
- 1998: December
- 1994: February

Reviewed Dates:

- 2024: July Annual review completed. No changes. References and coding updated.
- 2023: July
- 2022: July
- 2021: October
- 2020: October
- 2019: October (unarchived)
- 2001: November
- 2000: November
- 1999: November
- 1996: August

Effective Date:

June 1992

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

§ 874.3620 Ear, nose, and throat synthetic polymer material. (2024, Mar 22). Retrieved Jun 25, 2024, from Code of Federal Regulations: https://www.ecfr.gov/current/title-21/section-874.3620

(2024). Retrieved Jun 24, 2024, from Hayes:

https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522penile%2520implant%2522,%2522title %2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%252

(2024, Mar 14). Retrieved Jun 24, 2024, from MCG: https://careweb.careguidelines.com/ed27/index.html

Durable Medical Equipment (DME) - Chapter IV: Covered Services and Limitations. (2024, Jan 04). Retrieved Jun 24, 2024, from Department of Medical Assistance Services - MES Public Portal: https://vamedicaid.dmas.virginia.gov/sites/default/files/2024-01/DME%20Chapter%20IV%20%28updated%201.4.24%29 Final.pdf

Erectile Dysfunction: AUA Guideline (2018). (2018). Retrieved Jun 24, 2024, from American Urological Association: https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-(ed)-guideline

Lazarou, S. (2023, Nov 14). Surgical treatment of erectile dysfunction. Retrieved Jun 24, 2024, from UpToDate: <a href="https://www.uptodate.com/contents/surgical-treatment-of-erectile-dysfunction?search=penile%20implant&source=search_result&selectedTitle=1%7E19&usage_type=default&display_rank=1#H2

NCD: Diagnosis and Treatment of Impotence (230.4). (N.D.). Retrieved Jun 24, 2024, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-

Surgical 23 Page 4 of 5

results.aspx?keyword=Substernal&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD, 6,3,5,1,F,P&contractOption=all&sortBy=relevance

Product Code: MIB. (2024, Jun 24). Retrieved Jun 25, 2024, from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

SHP Penile Prosthesis Surgery, SHP Surgical 23, Implant, semi-rigid penile prosthesis, inflatable penile prosthesis, implantable penile pumps, penile implant, Reimplantation, noninflatable penile prosthesis, Penile implant, implantable penile pumps, inflatable penile prosthesis (IPP), Malleable implants, Penile co-implanted (fluid reservoir and a pump)

Surgical 23 Page 5 of 5