

Penile Implants (Implantation, Repair, Removal)

Penile implants are typically recommended after other treatments for erectile dysfunction fail. Depending on the cause of the condition, treatment may be surgical - e.g., implantation of a penile prosthesis (implant), or non-surgical - e.g., medical or psychotherapeutic treatment.

Note: Penile implants performed as part of gender affirming surgeries are **NOT** covered under this clinical criteria.

I. Criteria for Initial Approval

Penile implantation or removal, will be considered for coverage when **all** of the criteria below are met, confirmed with supporting medical documentation.

- Coverage will be considered with documentation that medical therapies and or psychotherapeutic treatments have been tried and failed, and when **one** of the following medical (organic) etiologies of erectile dysfunction (ED) exists.
 - **Medical documentation of failed treatment:**
 - Testosterone replacement therapy using topical creams, patches or IM injections; OR
 - PDE5 inhibitors.
 - **Etiologies of ED:**
 - Vascular impotence due to one of the following:
 - Hypertension;
 - Intrapenile arterial disease;
 - Penile fracture;
 - Peyronie's disease;
 - Smoking; or
 - Status post cavernosal infection.
 - Neurogenic impotence due to one of the following:
 - Diabetes;
 - Fractured pelvis;
 - Major surgery of the pelvis, retroperitoneum, radical prostatectomy, or colorectal surgery;
 - Multiple sclerosis;

- Spina bifida;
 - Spinal cord injury/disease; or
 - Syringomyelia.
- Other Medical/Hormonal Reasons due to one of the following:
 - Diabetes mellitus;
 - Peripheral neuropathy;
 - Peripheral vascular disease of the pelvis or extremity;
 - Spinal cord injury;
 - Pelvic perineal injuries of the genital or urinary tract;
 - Arteriosclerosis;
 - Medications related to ED that are required to treat other medical conditions; or
 - Endocrine-caused related to hypogonadism (hyperprolactinemia, hypothyroidism, and hyperthyroidism).
 - Treatment-induced impotence due to one of the following:
 - Radiation therapy to the pelvis or retroperitoneum;
 - Radiation therapy due to prostate cancer causing impotence;
 - Postoperative bilateral sympathectomy; or
 - Post-prostatectomy.

Penile Implant Repair or Removal

Penile Prosthetic Implant repair or removal is considered medically necessary when:

- Any of the following are met:
 - Infection;
 - Mechanical failure (malfunction/break);
 - Urinary obstruction; or
 - Intractable pain;
- All other medical necessity criteria are required to be met; and
- If penial replacement is not part of the manufacturer's warranty.

II. Required Clinical Information

Documentation of **ALL** of the following:

- Medical history must include documentation of the medical workup of penile dysfunction. Documentation should include:
 - Medical records related to diagnosis and medical necessity;

- Results of all related laboratory tests and radiologic imaging used to confirm diagnosis and medical necessity;
 - Absence of active alcohol or substance abuse;
 - Absence of drug-induced impotence related to the **inappropriate** use of anabolic steroids, anticholinergics, antidepressants, antipsychotics or central nervous system depressants;
 - Absence of untreated depression or psychiatric illness; and
 - Documentation of all medicinal and nonsurgical methods that have proven ineffective or are contraindicated (e.g., past treatments and results of treatments to include pharmacotherapy, medical devices, etc.)
- Recommendation for an FDA approved penile prosthesis

III. Coverage Limitations and Exclusions

Penile implantation and removal will not be covered for any indications not listed above.

IV. Length of Authorization for Initial Therapy

Penile implantation and removal will be authorized for 6 months when criteria for initial approval are met.

V. Billing Code/Information

See below for a list of CPT/HCPCS codes:

54400	INSERTION OF PENILE PROSTHESIS; NON-INFLATABLE
54401	INSERTION OF PENILE PROSTHESIS; INFLATABLE
54405	INSERTION OF MULTI-COMPONENT, INFLATABLE PENILE PROSTHESIS
54408	REPAIR OF COMPONENTS OF MULTI-COMPONENT, INFLATABLE PENILE PROSTHESIS
54410	REMOVAL AND REPLACEMENT OF ALL COMPONENTS OF A MULTI-COMPONENT, INFLATABLE PENILE PROSTHESIS
54411	REMOVAL AND REPLACEMENT OF ALL COMPONENTS OF A MULTI-COMPONENT, INFLATABLE PENILE PROSTHESIS THROUGH AN INFECTED FIELD, INCLUDING IRRIGATION AND DEBRIDEMENT OF INFECTED TISSUE
54415	REMOVAL OF NON-INFLATABLE OR INFLATABLE PENILE PROSTHESIS, WITHOUT REPLACEMENT OF PROSTHESIS
54416	REMOVAL AND REPLACEMENT OF NON-INFLATABLE OR INFLATABLE PENILE PROSTHESIS

54417	REMOVAL AND REPLACEMENT OF NON-INFLATABLE OR INFLATABLE PENILE PROSTHESIS THROUGH AN INFECTED FIELD, INCLUDING IRRIGATION AND DEBRIDEMENT OF INFECTED TISSUE
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Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 9/28/2021

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