Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Penile Prosthesis Implantation for Erectile Dysfunction (ED)	**MP-SU-FP-06-26**	☒ **MMM MA** ☐ **MMM MultiHealth**	**07/31/2026**	**07/31/2026**
			Last Review Date:	**Frequently Revision:**
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Service Category:

☐ Anesthesia
☒ **Surgery**
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☐ Other: _____

Service Description:

This policy establishes Internal Coverage Criteria (ICC) for penile prosthesis implantation as a surgical reconstructive intervention for the treatment of erectile dysfunction (ED) of organic, neurogenic, vascular, or mixed etiology when clinically appropriate conservative management has failed, is contraindicated, not tolerated, or otherwise not clinically appropriate.

Services covered under this policy include:
• Primary penile prostheses (semi-rigid or inflatable)
• Penile prosthesis replacement due to mechanical failure, infection, or other medical indication
• Removal and reimplantation in the context of medical complications
• Surgical management associated with infection or device failure

***Note*:** Vacuum erection devices (L7900) and related accessories (L7902) are addressed under applicable Medicare DME coverage guidance, including LCD - L34824 and are not covered under this policy.

Background Information:

This Internal Coverage Criteria (ICC) policy establishes the Plan's Internal Coverage Criteria (ICC) for penile prosthesis implantation pursuant to 42 CFR §422.101(b)(6). It operationalizes NCD 230.4 through evidence-based clinical criteria aligned with the AUA 2018 Guideline, current peer-reviewed literature, and applicable Medicare coverage considerations. These criteria apply to prior authorization review, concurrent review, and retrospective review activities [1-3]. Coverage determinations are additionally subject to the "reasonable and necessary" standard under §1862(a)(1)(A) of the Social Security Act.

Applicable National Coverage Determination
The applicable NCD is NCD 230.4 – Diagnosis and Treatment of Impotence (CMS Pub. 100-3, effective 01/01/1966) [2]. The NCD establishes that program payment may be made for the diagnosis and treatment of sexual impotence, and that treatment may be surgical (e.g., implantation of a penile prosthesis) or nonsurgical. The NCD does not establish specific clinical criteria for medical necessity, required prior therapies, diagnostic thresholds, or device selection standards [3].

This Internal Coverage Criteria (ICC) is based on:
• American Urological Association (AUA) Erectile Dysfunction Guideline, 2018 [4]
• EAU–AUA Perspectives on Erectile Dysfunction Surgery (Medina-Polo et al., 2020) [5]
• International Penile Prosthesis Implantation Consensus Forum (Chung et al., 2022) [6]
• Peer-reviewed clinical literature cited

Psychiatric Services Limitation
Consistent with NCD 230.4, psychiatric service limitations applicable to outpatient mental health services remain subject to CMS Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, Section 30 [3,7].

Psychiatric and behavioral health services associated with erectile dysfunction remain subject to all applicable Medicare mental health coverage requirements, benefit limitations, and medical necessity criteria. Coverage of penile prosthesis implantation does not expand, replace, or otherwise alter Medicare coverage criteria for psychiatric evaluation, psychotherapy, psychiatric hospitalization, or other behavioral health services.

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Definition and Epidemiology

Erectile dysfunction (ED) is defined by American Urological Association (AUA) as the consistent or recurrent inability to attain and/or maintain a penile erection sufficient for satisfactory sexual performance. According to the American Urological Association (AUA), ED affects more than 30 million men in the United States and is frequently associated with cardiovascular and metabolic comorbidities, including hypertension, diabetes mellitus, dyslipidemia, obesity, smoking, depression, and sedentary lifestyle habits [4].

Pathophysiology and Associated Conditions

The etiology of ED is often multifactorial and may include vascular, neurogenic, hormonal, psychogenic, medication-related, and anatomical causes. Vascular disease represents one of the most common underlying mechanisms associated with ED. Diabetes mellitus, hypertension, dyslipidemia, lower urinary tract symptoms (LUTS), depression, and psychosocial factors are commonly associated conditions. The AUA guideline emphasizes that ED may also represent an early marker of underlying cardiovascular disease and may precede future cardiovascular events. [4]

Treatment Framework and Shared Decision-Making

The American Urological Association (AUA) guideline supports a shared decision-making model for the management of erectile dysfunction (ED). Patients should be informed of all medically appropriate treatment options, including conservative therapy, pharmacologic therapy, vacuum erection devices, injectable therapies, intraurethral therapy, and penile prosthesis implantation [4].

Treatment selection should remain individualized and based on clinical appropriateness, treatment response, contraindications, patient preference, comorbidities, and informed discussion of risks, benefits, and alternative treatment options.

Clinical evaluation and treatment planning may include review of prior therapeutic response, history of medical therapy, contraindications, intolerance, adverse effects, and patient-specific clinical factors. Supporting clinical documentation may include prior treatment history, therapeutic response, shared decision-making discussions, and evaluation by a urologist or other appropriately qualified specialist experienced in the management of erectile dysfunction and penile prosthesis implantation, when clinically appropriate to support treatment planning, counseling, device selection, and surgical candidacy assessment [4,6].

Lifestyle interventions, including weight reduction, smoking cessation, dietary modification, and increased physical activity, may improve overall health and erectile function [4].

Penile prosthesis implantation is generally considered in patients with medically refractory ED, contraindications or intolerance to less invasive therapies, lack of clinical appropriateness of conservative management, or informed patient preference following counseling and shared decision-making.

Irreversible Structural / Organic Injury

Certain irreversible structural or organic injuries may result in severe erectile dysfunction that is unlikely to respond to conservative therapy. Examples described in the literature include significant pelvic or perineal trauma, corporal fibrosis following priapism, post-surgical corporal fibrosis, and other irreversible structural penile injuries. In these clinical scenarios, penile prosthesis implantation may represent an appropriate definitive treatment option when clinically indicated [4,6].

Clinical Role of Penile Prosthesis in the Management of Erectile Dysfunction

According to the American Urological Association (AUA) Guideline (2018), penile prosthesis implantation is an effective treatment option for men with medically refractory erectile dysfunction or for those with contraindications, intolerance, or lack of clinical appropriateness of less invasive treatment options. Selection of surgical therapy should be individualized and based on clinical findings, prior treatment response, patient preferences, and shared decision-making between the patient and the treating physician [4].

Prior to surgery, patients should receive comprehensive counseling regarding:

- Risks and benefits of penile prosthesis implantation
- Medically appropriate alternative treatment options

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- Expected postoperative outcomes and functional expectations
- Potential device-related complications, including mechanical failure, erosion, and the possible need for future revision or replacement procedures
- Infection risk and strategies to reduce perioperative complications

Appropriate patient selection and comprehensive preoperative counseling are considered essential components of optimal surgical outcomes and informed decision-making. Consistent with current evidence-based recommendations, penile prosthesis implantation should not be performed in the presence of an active systemic infection, cutaneous infection involving the operative field, or untreated urinary tract infection [4,6].

Investigational Therapies

The AUA Guideline (2018) identifies the following therapies as investigational, experimental, or supported by insufficient evidence for routine treatment of erectile dysfunction:

- Low-intensity extracorporeal shock wave therapy (Li-ESWT)
- Intracavernosal stem cell therapy
- Platelet-rich plasma (PRP) therapy

Types of Penile Prostheses

Penile prostheses are generally categorized as inflatable or non-inflatable/malleable devices. Device selection is based on patient anatomy, comorbidities, manual dexterity, functional expectations, prior pelvic or penile implantation, corporal fibrosis, surgeon experience, and shared decision-making [4,6].

Device Type	Description	Clinical Notes
Inflatable 3-piece (IPP-3)	Cylinders + scrotal pump + abdominal reservoir	Accounts for >90% of contemporary U.S. implants. Highest patient and partner satisfaction rates.
Inflatable 2-piece	Cylinders + pump (no separate reservoir)	Alternative when abdominal reservoir placement is contraindicated or not feasible.
Malleable (semi-rigid)	Permanently firm; manually positioned	Simpler mechanism; preferred for patients with limited manual dexterity or elevated surgical risk.

FDA Regulatory Status

Penile prosthetic devices are regulated by the U.S. Food and Drug Administration (FDA). Noninflatable penile rigidity implants (malleable or semirigid prostheses) are classified as Class II medical devices under 21 CFR §876.3630 and are subject to special controls and 510(k) requirements. Inflatable penile prostheses are classified as Class III medical devices under 21 CFR §876.3350 and require Premarket Approval (PMA) due to higher associated surgical and device-related risks, including infection, erosion, and mechanical failure [8,10].

Clinical Evidence Summary

Evidence supporting penile prosthesis implantation is derived primarily from observational studies, registry data, systematic reviews, and long-term cohort analyses. [4] Published evidence consistently demonstrates high patient and partner satisfaction rates, durable long-term device performance, and clinically meaningful improvement in erectile function and quality of life among appropriately selected patients.[5,6,11-16].

Inflatable penile prostheses demonstrate high long-term mechanical reliability, with most studies reporting acceptable device survival beyond 10 years [13]. Infection remains the most significant prosthesis-related complication; however, modern antibiotic-coated devices have substantially reduced infection rates [11].

Risk factors associated with increased prosthetic complications include uncontrolled diabetes mellitus, obesity, immunosuppression, corporal fibrosis, spinal cord injury, prior pelvic radiotherapy, chronic urinary catheterization, and complex reconstructive surgery [6,14]. Optimization of modifiable risk factors prior to implantation is recommended to reduce perioperative and long-term complications [6].

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Published evidence also supports the effectiveness of penile prosthesis implantation in special populations, including men with Peyronie disease, spinal cord injury, diabetes mellitus, and post-prostatectomy erectile dysfunction [5,6,15,16].

Peyronie Disease associated with Erectile Dysfunction

Peyronie disease (PD) is a chronic fibrotic disorder of the tunica albuginea associated with penile curvature, pain, deformity, psychological distress, and frequently associated with erectile dysfunction. Major urological guidelines generally agree that surgical intervention for PD should be considered after disease stabilization and when deformity or erectile dysfunction causes functional impairment. In men with PD and erectile dysfunction that is unresponsive to pharmacologic or conservative therapy, penile prosthesis implantation is recognized as the preferred surgical option, with adjunctive straightening procedures considered when clinically indicated. Shared decision-making, objective assessment of deformity, and thorough preoperative counseling are essential prior to surgery [16].

Endocrine Evaluation and Laboratory Testing

Consistent with the AUA Guideline, selective laboratory evaluation may be clinically appropriate to identify potentially reversible causes of erectile dysfunction prior to surgical intervention. Morning serum total testosterone testing is recommended in men with ED when clinically indicated to evaluate for testosterone deficiency and guide management [4,18]. Additional endocrine or laboratory testing, including prolactin or thyroid studies, may be performed based on clinical presentation, associated symptoms, or suspected underlying endocrine disorders [4,18,19].

Expectation Management

Given the invasive and largely irreversible nature of penile prosthesis implantation, structured preoperative expectation counseling should be part of the evaluation process. Counseling should include discussion of: (a) permanent alteration of natural erectile physiology; (b) possible perceived penile length changes; (c) the mechanical nature of prosthetic rigidity rather than restoration of neurovascular erectile function; and (d) potential future revision, replacement, or device-related complications [4,6].

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Medical Necessity Guidelines:

Penile prosthesis implantation may be considered medically necessary when clinically reasonable and necessary for the treatment of erectile dysfunction (ED) or impotence consistent with National Coverage Determination (NCD) 230.4 and when the clinical documentation supports the criteria established in this policy.

These criteria constitute Internal Coverage Criteria (ICC) developed pursuant to 42 CFR §422.101(b)(6) and are informed by current evidence-based clinical guidelines, including the American Urological Association (AUA) Erectile Dysfunction Guideline, peer-reviewed literature, FDA-regulated therapies and devices, and applicable Medicare coverage considerations [2-6,16].

Clinical evaluation and treatment selection should remain individualized and based on documented erectile dysfunction resulting in clinically significant functional impairment, prior treatment response, contraindications, intolerance to therapy, patient-specific clinical factors, and shared decision-making.

Consistent with current clinical practice, erectile dysfunction is generally expected to be persistent for approximately six months or longer, when clinically appropriate, prior to consideration of penile prosthesis implantation [21].

Supporting clinical documentation may include medical, sexual, and psychosocial history; prior treatment history and therapeutic response; evaluation by a urologist or other appropriately qualified specialist experienced in the evaluation and management of erectile dysfunction, such as interventional radiology, psychology, behavioral health, endocrinology, rehabilitation medicine, or other relevant specialty when clinically appropriate; documentation of relevant organic, structural, neurogenic, vasculogenic, endocrinologic, post-surgical, or mixed etiologies; physical examination findings; and clinically appropriate laboratory evaluation when indicated [4,6,18].

Patients should be informed of medically appropriate treatment alternatives and participate in shared decision-making regarding available treatment options. Clinical documentation should support discussion of risks, benefits, limitations, alternative treatment options, device selection, potential device-related complications, infection risk, and post-operative expectations. Behavioral health or psychosexual evaluation may be considered when psychogenic factors are suspected to contribute to erectile dysfunction or when clinically appropriate to support treatment planning [4,6].

This policy does not establish mandatory step therapy requirements, mandatory failure of all conservative treatment modalities, or a fixed treatment sequence prior to consideration of penile prosthesis implantation.

INITIAL PENILE PROSTHESIS IMPLANTATION

Penile prosthesis implantation may be considered medically necessary when documentation supports the following:

A. Conservative Therapy Assessment

Documentation must support **one or more** of the following:

- □ Failure of clinically appropriate conservative therapy; **or**
- □ Inadequate therapeutic response; **or**
- □ Contraindication to conservative therapy; **or**
- □ Intolerance or adverse effects related to clinically appropriate conservative treatment alternatives; **or**
- □ Conservative management is not clinically appropriate; **or**
- □ Shared decision-making supporting penile prosthesis implantation following counseling regarding medically appropriate treatment alternatives, supported by clinical documentation reflecting discussion of treatment options, risks, benefits, limitations, and patient preference.

Examples of conservative treatment alternatives may include:

- □ Oral phosphodiesterase type 5 (PDE5) inhibitor therapy
- □ Intracavernosal injection therapy
- □ Intraurethral therapy (e.g., alprostadil urethral suppository [MUSE®])

Note: Vacuum erection devices (VED) may be discussed as part of the clinical management of erectile dysfunction; however, Medicare coverage is subject to LCD L34824 and applicable statutory limitations.

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REPLACEMENT / REVISION / REIMPLANTATION CRITERIA

B. Replacement, revision, removal, or reimplantation of a previously implanted penile prosthesis may be considered medically necessary when **one or more** of the following apply:

- □ Documented mechanical failure
- □ Prosthesis infection requiring device removal
- □ Component erosion or extrusion
- □ Medically necessary revision is supported by urologic documentation and clinical findings consistent with device-related complication or dysfunction.
- □ Salvage replacement procedure may be considered when clinically appropriate and supported by urologic documentation.

SPECIAL POPULATIONS – (ADDITIONAL CLINICAL CONSIDERATIONS)

C. Peyronie Disease with Erectile Dysfunction:

Penile prosthesis implantation may be considered medically necessary in members with Peyronie disease and coexisting erectile dysfunction when **all** the following are met:

- □ Functional impairment is documented; **and**
- □ Coexisting erectile dysfunction meets the general medical necessity criteria for penile prosthesis implantation; **and**
- □ Disease stability is documented when clinically applicable; **and**
- □ Shared decision-making and preoperative counseling are documented, including discussion of expected outcomes and possible adjunctive straightening maneuvers.

D. Post-Prostatectomy / Post-Radiation Erectile Dysfunction

Persistent erectile dysfunction following radical prostatectomy or pelvic radiotherapy may qualify when:

- □ The general medical necessity criteria are met; **and**
- □ Clinically appropriate conservative management has failed, is contraindicated, not tolerated, or not clinically appropriate.

E. Irreversible Structural or Organic Injury

Penile prosthesis implantation may be considered medically necessary when irreversible organic injury is documented and conservative management is ineffective, contraindicated, not tolerated or otherwise not clinically appropriate, **including but not limited to:**

- □ Significant pelvic or perineal trauma; **or**
- □ Priapism with corporal fibrosis; **or**
- □ Progressive corporal fibrosis following radical pelvic surgery or other irreversible structural injury.

When Not Medically Necessary:

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

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Limitations and Restrictions:

1. Prior authorization is required for services addressed under this policy.
2. Vacuum erection devices (VED) and related accessories are addressed under applicable Medicare DME coverage policies and are outside the scope of this policy. Refer to Medicare LCD L34824 – Vacuum Erection Devices (VED). Consistent with Medicare coverage guidance, vacuum erection devices are statutorily non-covered for dates of service on or after July 1, 2015.
3. The following therapies are considered investigational, experimental, or not medically necessary due to insufficient evidence and/or lack of FDA approval for this indication [4-6,16]:
   - □ Low-intensity extracorporeal shock wave therapy (ESWT)
   - □ Platelet-rich plasma (PRP) therapy
   - □ Stem cell therapy
4. The intended use is cosmetic or enhancement (penile augmentation for appearance, size, or sexual performance in the absence of documented functional ED) [4-6].

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan documents and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
N52.01	Erectile dysfunction due to arterial insufficiency
N52.02	Erectile dysfunction due to venous leak
N52.03	Erectile dysfunction due to combined arterial insufficiency and corporo-venous occlusive dysfunction
N52.1	Erectile dysfunction due to diseases classified elsewhere
N52.8	Other male erectile dysfunction
N52.9	Male erectile dysfunction, unspecified
N48.6	Induration penis plastic (Peyronie disease)
Z96.698	Presence of other specified functional implants

CPT Codes:

Codes	Description
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
54406	Removal of all components of a multi-component inflatable penile prosthesis without replacement
54407	Removal and replacement of all components of a multi-component inflatable penile prosthesis at the same operative session
54408	Repair of component of multi-component penile prosthesis
54410	Removal and replacement of all components 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
54415	Removal of non-inflatable (semi-rigid) penile prosthesis without replacement

HCPCS Codes:

Codes	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable

Note: L8699 may be used when a more specific HCPCS code is not applicable and is subject to applicable Medicare billing guidance and documentation requirements.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	New Internal Coverage Criteria (ICC) developed pursuant to 42 CFR §422.101(b)(6). Applicable National Coverage Determination (NCD) 230.4 establishes Medicare coverage for the diagnosis and treatment of impotence, including penile prosthesis implantation; however, the NCD does not define specific clinical medical necessity criteria, treatment sequencing requirements, or device-selection standards. No applicable Local Coverage Determination (LCD) establishing specific medical necessity criteria for penile prosthesis implantation was identified within the applicable Medicare Administrative Contractor (MAC) jurisdiction at the time of policy development. Internal Coverage Criteria (ICC) were developed based on current evidence-based clinical guidelines, peer-reviewed literature, FDA regulatory requirements, applicable Medicare coverage guidance, and published international consensus recommendations regarding penile prosthesis implantation. This policy establishes the applicable regulatory framework, clinical background information, medical necessity criteria, documentation requirements, limitations and restrictions, investigational/non-covered services, and applicable coding guidance for penile prosthesis implantation.	N/A	7/31/2026