

Title: Penile Prosthesis Implantation	Division: Medical Management Department: Utilization Management
Approval Date: 10/26/2018	LOB: Medicaid, Medicare, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP
Effective Date: 10/26/2018	Policy Number: UM-MP238
Review Date: 10/2/2021	Cross Reference Number:
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1. POLICY DESCRIPTION:

Penile Prosthesis Implantation Secondary to Erectile Dysfunction (ED)

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS:

Impotence is a failure of the penis for which the diagnosis, and frequently the treatment, require medical expertise. Depending on the cause of the condition, treatment may be surgical; e.g., implantation of a penile prosthesis, or nonsurgical; e.g., medical or psychotherapeutic treatment.

Erectile dysfunction (ED) ED is defined as the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance.

4. POLICY:

Penile Prosthesis Implantation Secondary to Erectile Dysfunction (ED) will be considered medically necessary for beneficiaries with documented physiologic ED when all of the following criteria are met.

1. Absence of:
 - a. active alcohol or substance abuse; and
 - b. Drug induced impotence related to: anabolic steroids, anticholinergics, antidepressants, antipsychotics or central nervous system depressants; **and**
 - c. Untreated depression or psychiatric illness.
2. Nonsurgical methods have proven ineffective or are contraindicated.
3. Normal prolactin and thyroid hormone levels.
4. Normal serum testosterone levels (low testosterone suggests treatable endocrine cause of impotence).
5. History of organic disease including **any** of the following:
 - a. Documented injury to perineum/genitalia; or
 - b. Major pelvic trauma affecting bladder and/or anal and/or erection control; or
 - c. Major vascular surgery involving aorta or femoral blood vessels; or
 - d. Neurological disease (e.g., diabetic neuropathy); or
 - e. Peyronie's disease; or
 - f. Renal failure; or

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- g. Secondary to spinal cord injury; or
- h. Status post prostate, bladder, bowel or spinal surgery; or
- i. Vascular insufficiency or venous incompetence documented by dynamic infusion cavernosometry and cavernosography (DICC); or
- j. Venous leak of the penis.

Additional Considerations:

1. Patients with sickle cell anemia who have stuttering priapism and/or cavernosal scarring are also potential candidates for inflatable penile prosthesis, which offers not only a cure for their priapism but also a close approximation to normal appearance and function.
2. Further considerations for optimizing outcome include selecting patients whose etiology is previous pelvic trauma and patients who are young, do not have diabetes, do not smoke, and have no underlying neurologic disease.
3. Removal of a penile implant is considered medically necessary if the prosthesis, is affected, intractable pain, mechanical failure, or urinary obstruction.
4. Reimplantation of a penile prosthesis is considered medically necessary for persons who meet medical necessity criteria above for a penile prosthesis and whose prior prosthesis was removed for medically necessary indications.
5. Implantable penile prostheses are considered experimental and investigational for other indications because their effectiveness for indications other than the criteria listed above has not been established.

5. LIMITATIONS/ EXCLUSIONS:

ERECTILE DYSFUNCTION DRUGS NO LONGER COVERED

The **Medicaid program** is prohibited from covering drugs used for the treatment of sexual or erectile dysfunction, unless such drugs are used to treat other conditions, and have received approval from the Food and Drug Administration (FDA) for that purpose.

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CONVICTED SEX OFFENDERS MEDICAID – NYS

The Medicaid program will not provide coverage for erectile dysfunction (ED) drugs, procedures or supplies to convicted sex offenders. Prior approval is required for the following CPT/HCPCS procedure codes.

Medicare Prescription Drug Benefit Manual, Chapter 6, Section 20.1 - Excluded Categories

Prescription or injectable medications for the treatment of sexual or erectile dysfunction are not covered. ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off-label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System. Examples include, but are not limited to:

- a. Alprostadil urethral suppository (MUSE)
- b. Viagra
- c. Testosterone patches
- d. Caverject
- e. Papaverine
- f. Regitine

6. APPLICABLE PROCEDURE CODES:

CPT	Description
37788	Penile revascularization, artery, with or without vein graft
37790	Penile venous occlusive procedure
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

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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
J0270	Injection, alprostadil, 1.25 mcg (aka Caverject)
J0275	Alprostadil urethral suppository (aka MUSE)
J2440	Injection, papaverine hcl, up to 60 mg
J2760	Injection, phentolamine mesylate, up to 5 mg
L7900	Vacuum erection system

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
F52.0	Hypoactive sexual desire disorder
F52.21	Male erectile disorder
F52.32	Male orgasmic disorder
N52.01	Erectile dysfunction due to arterial insufficiency
N52.02	Corporo-venous occlusive erectile dysfunction
N52.03	Combined arterial insufficiency and corporo-venous occlusive erectile dysfunction
N52.1	Erectile dysfunction due to diseases classified elsewhere
N52.2	Drug-induced erectile dysfunction
N52.31	Erectile dysfunction following radical prostatectomy
N52.32	Erectile dysfunction following radical cystectomy
N52.33	Erectile dysfunction following urethral surgery
N52.34	Erectile dysfunction following simple prostatectomy
N52.35	Erectile dysfunction following radiation therapy

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N52.36	Erectile dysfunction following interstitial seed therapy
N52.37	Erectile dysfunction following prostate ablative therapy
N52.39	Other and unspecified postprocedural erectile dysfunction
N52.8	Other male erectile dysfunction
N52.9	Male erectile dysfunction, unspecified
0VUSX7Z-	Supplement Penis with Autologous Tissue Substitute, External Approach
0VUSXJZ-	Supplement Penis with Synthetic Substitute, External Approach
0VUSXKZ	Supplement Penis with Nonautologous Tissue Substitute, External Approach
0VUS0JZ	Supplement Penis with Synthetic Substitute, Open Approach
0VUS4JZ	Supplement Penis with Synthetic Substitute, Percutaneous Endoscopic Approach

8. REFERENCES:


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REVISION LOG:

REVISIONS	DATE
Creation date	
Annual Review	10/25/19
Annual Review	10/2/2020

Approved: <i>Bruce Sosler</i>	Date:	Approved: 	Date: 10/5/2020
Bruce Sosler, MD Clinical Medical Director	10/2/2020	Sanjiv Shah, MD Chief Medical Officer	

Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review

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criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan 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). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program 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 MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.