MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Erectile Dysfunction**
Policy Number	**7.01.30**
Category	**Contract Clarification**
Original Effective Date	**10/18/01**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Treatment

I. Based upon our criteria and assessment of peer-reviewed literature, the following treatment modalities have been medically proven to be effective and, therefore, are considered **medically appropriate** for patients with known erectile dysfunction (ED) whose symptoms have lasted more than six (6) months (See Policy Guidelines for treatment prior to six (6) months):
   A. Oral Drug Therapy (i.e., sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis);
   B. Intracavernous Injection Therapy (e.g., Caverject, Edex);
   C. Transurethral Delivery System (i.e., Medicated Urethral System for Erection [MUSE]);
   D. Vacuum Constriction Devices (i.e., ErecAid);
   E. Penile Prosthetic Implants (i.e., semi-rigid, malleable and inflatable): Only medically appropriate in patients who fail or refuse other forms of therapy. Penile prosthesis implantation should not be performed in men with psychogenic ED, unless a psychiatrist or psychologist participates in the preoperative evaluation and concurs with the need for prosthesis implantation;
   F. Arterial Revascularization: Only medically appropriate in men with normal corporeal venous function who have arteriogenic ED secondary to pelvic or perineal trauma.

II. Based upon our criteria and assessment of peer-reviewed literature, electroejaculation is considered **medically appropriate** for the following indications:
   A. For men with spinal cord injury who desire to become biological fathers;
   B. The inability to ejaculate is a consequence of retroperitoneal lymph node dissection (REPLND);
   C. Insulin-dependent diabetes;
   D. Multiple Sclerosis (MS);

E. Spina bifida or other neural tube deficit, complications due to bladder or rectal surgery, or idiopathic anejaculation (neurogenic, psychogenic or a combination of both).

III. Based upon our criteria and assessment of peer-reviewed literature, the following treatment modalities have not yet demonstrated a benefit to patient outcomes and are considered **not medically necessary** for the treatment of ED:

A. Topical medications containing vasodilators;
B. Arterial (penile) revascularization, except for the indication listed above in Policy Statement I.F;
C. Venous ligation in the treatment of venous leak impotency (venous ligation attempts to close off the natural drainage of the penis to maintain blood in the penis during an erection);
D. Crural ligation for primary venous leakage ED;
E. Temporary or permanent lumbar ganglionic block or sympathectomy for ED secondary to cavernous adrenergic hypertone.

IV. Based upon our criteria and assessment of peer-reviewed literature, all of the following treatment modalities have not been medically proven to be effective and, therefore, are considered **investigational** for patients with ED or Peyronie's Disease, including but not limited to:

A. Extracorporeal Shock Wave Therapy (ESWT);
B. Penile contracture devices (e.g., RestoreX).

Diagnosis

V. Based upon our criteria and assessment of peer-reviewed literature, the following procedures are considered **medically appropriate** in the diagnosis of ED in the following circumstances:

A. Nocturnal penile tumescence (NPT) test, **only** when the clinical evaluation is unable to distinguish psychogenic from organic impotence;
B. Duplex scan in conjunction with intracorporeal papaverine;
C. Pharmacological response test (PRT) using vasoactive medications such as papaverine HCL, prostaglandin E1;
D. Dynamic infusion cavernosonogram and cavernosometry, for patients who meet the criteria for penile revascularization;
E. Pudendal arteriography/angiography, for patients who meet the criteria for penile revascularization;
F. Penile biothesiometry (considered an integral part of evaluation and management during an office visit).

VI. Based upon our criteria and assessment of peer-reviewed literature, the following procedures are considered **not medically necessary** in the diagnosis of ED:

A. Dorsal nerve conduction latencies;
B. Penile plethysmography;
C. Cavernosal nerve mapping;
D. Evoked potential measurements;
E. Corpora cavernosal electromyography.

Refer to Corporate Medical Policy #7.02.02 Allogeneic Hematopoietic (STEM) Cell Transplantation

Refer to Pharmacy Management Drug Policy for Quantity Limit (PHARMACY-43)

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Treatment may be initiated prior to six (6) months, in the case of an acute event such as penile trauma or radical pelvic surgery (e.g., prostatectomy or cystectomy), or in the case of drug-induced ED caused by treatment of a co-morbid condition.

II. The least invasive procedure should be the first line of treatment. If a member fails oral therapy, a durable medical equipment (DME) modality should generally be the next step in treatment.

III. Vacuum constriction devices are considered to be durable medical equipment.

IV. The following treatment modalities are dependent upon a member's subscriber contract with a prescription drug benefit: oral drug therapy, intracavernous injection therapy, and transurethral delivery system. (Refer to Pharmacy Management for information regarding coverage of oral drug therapy).

V. With the exception of oral drug therapy, a statement of medical necessity from the urologist is required documenting results of clinical evaluation and any diagnostic test results.

VI. Oral drugs such as Sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis) inhibit (block) the effect of an enzyme, phosphodiesterase-5 (PDE5), causing an increase in penile blood flow necessary for an erection.
   A. PDE5 inhibitors should not be used in combination with other treatment modalities for ED.
   B. PDE5 inhibitors are contraindicated if the patient is actively taking nitrates in any form.
   C. PDE5 inhibitors should be used with caution in patients who take alpha-blockers.
   D. Vardenafil should be used with caution if a patient, or a patient's family member, has a rare heart condition known as "prolongation of the QT interval."

VII. Patients using vasoactive drug injection therapy should be informed that a prolonged erection can occur and that they should present for treatment if the erection lasts longer than four (4) hours such as papaverine, phentamine, and/or prostaglandin E1 (alprostadil).

DESCRIPTION

In 2008, New York State mandated that Medicaid, Family Health Plus, Healthy New York, and standardized HMO and HMO/POS direct payment policies exclude coverage of drugs, procedures, and supplies for the treatment of ED when provided to, or prescribed for use by, a person who is required to register as a sex offender under state law. In addition, in 2005, a federal law was enacted that excludes coverage of drugs to treat erectile dysfunction for all Family Health Plus enrollees.

ED, or impotence, is defined as the inability, over time, to consistently achieve or maintain an erection of sufficient rigidity for sexual penetration. ED involves the inability to achieve or maintain an erection and have sexual activity 80% of the time it is attempted.

ED may be psychogenic in origin; or caused by penile trauma, spinal cord injuries, abnormalities of the penis (e.g., penile fibrosis or Peyronie's disease), veno-occlusive dysfunction; or result from a radical pelvic surgery (e.g., radical prostatectomy or cystectomy). ED may also be a secondary symptom of a systemic disease or its treatment (e.g., diabetes mellitus, hypertension, blood lipid abnormalities, coronary artery disease or peripheral vascular disease). Brief, sporadic episodes of erectile failure are common occurrences and are often related to psychological stress.

The evaluation of a patient with ED usually consists of a structured interview and a thorough physical examination. Adjunctive testing, such as vascular assessment, neurological assessment, and monitoring of nocturnal erections, may be indicated in select patients.

Peyronie's Disease (PD)

PD is a localized connective tissue disorder of unknown cause and is characterized by the formation of inelastic fibrous plaques within the tunica albuginea or erectile tissue of the penis. For many patients, PD results in sexual problems due to the difficulty in attaining and/or maintaining erections.

Vacuum Constriction Devices

Penile vacuum devices (e.g., ErecAid) use a hand pump and cylindrical component to create a vacuum around the penis, drawing blood into the penis, which results in an erection.

Transurethral Delivery System

Medicated Urethral System for Erection (MUSE) is a method in which alprostadil (prostaglandin E1) is given transurethrally to treat ED.

Intracavernous Injection Therapy (e.g., Caverject, Edex) are vasodilating agents such as papaverine, phentamine, and/or prostaglandin E1 (alprostadil) are injected into the corpora of the penis to produce an erection.

Arterial Revascularization

Arterial revascularization refers to taking a blood vessel from another part of the body and using it to surgically bypass a blockage in the natural blood vessel of the penis.

Electroejaculation (EE)

Electroejaculation has had a large degree of success in enabling men with spinal cord injuries to become biological fathers. Up to 95% of men with spinal cord injury are unable to ejaculate normally. Vibratory and electrical stimulation, along with an appropriate method of semen collection followed by intrauterine insemination, has resulted in successful conception in a large number of cases.

ESWT

ESWT uses energy from the acoustic waves in a attempt to increase the expression of local growth factors, improving endothelial function, angiogenesis and potentially regenerating nerve fibers.

Penile Contracture Device

RestoreX is used for the treatment of Peyronie's disease and is also now available to correct penile curvature or indentation/hourglass deformity, restore penile length loss secondary to medical conditions or due to prior surgery/trauma, and to limit loss of erectile function post-prostatectomy.

RATIONALE

The American Urological Association (AUA) 2018 guidelines for Erectile Dysfunction state:

I. For men with ED, low intensity extracorporeal shock wave therapy (ESWT) should be considered investigational." (Conditional Recommendation; Evidence Level: Grade C"
II. For men with ED, intracavernosal stem cell therapy should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C.)"
III. For men with ED, platelet rich plasma (PRP) therapy should be considered experimental." (Expert Opinion).
IV. For young men with ED and focal pelvic/penile arterial occlusion and without documented generalized vascular disease or veno-occlusive dysfunction, penile arterial reconstruction may be considered. (Conditional Recommendation; Evidence Level: Grade C)
V. For men with ED, penile venous surgery is not recommended. (Moderate Recommendation; Evidence Level: Grade C)

Sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis) are phosphodiesterase type 5 inhibitors and are the only oral therapy approved by the FDA for the treatment of ED. No studies of topical creams, gels or compounded injections containing vasodilators provide evidence of their efficacy or safety for the treatment of men with ED, and they are not approved for this use by the FDA. Generic versions of Viagra, Cialis, and Levitra are currently available.

Phase III clinical trials of alprostadil topical cream for the treatment of mild to severe ED have recently concluded. Topical alprostadil cream appears to have improved ED in a broad range of patients and was safe and well-tolerated in the trials; however, it has not received U.S. Food and Drug Administration (FDA) approval for this use.

There is rarely any indication for the routine use of nocturnal penile tumescence (NPT) or rigidity testing. These tests have been difficult to standardize, and their actual benefit in determining therapy is unclear. NPT and rigidity testing may be useful in a patient who reports a complete absence of erections or when a primary psychogenic etiology is suspected. Ultrasound, angiography, and intracavernosal papaverine injections are widely used for the diagnosis of vasculogenic impotence, such as when a patient has sustained a groin trauma. Biothesiometry is the accepted technique for the neurological assessment of impotence. More extensive neurology tests, including nerve conduction latencies, evoked

potential measurements, and corpora cavernosal electromyography, are of limited clinical value and are usually not medically necessary for diagnostic purposes.

Low intensity extracorporeal shock wave therapy has been utilized by urologists since the 1980s for the non-invasive fragmentation of kidney stones in the form of extracorporeal shockwave lithotripsy (ESWL). Within the realm of sexual medicine there has been tremendous interest for LiSWT in the treatment of ED with a handful of preclinical studies followed by several clinical trials.

Vinay et al. (2021) conducted a randomized, double-blinded, sham -controlled study, the aim of the trail was to assess the effects of electromagnetic low-intensity (LI-ESWT) on the erectile dysfunction of vascular phosphodiesterase type 5 inhibitor (PDE5I) refractory ED patients. There were 76 participants with vascular PDE5I refractory ED, 40 were treated with LI-ESWT (one session/ week for 4 weeks, 5000 shocks/session, 0.09 mJ/mm^2 energy density), and 26 were treated with a sham probe. Three-month follow-up, median change in IIEF-EF score for active and sham groups was 3.5 (IQR 0–10) and −0.5 (IQR −11 to 1), respectively ($p<0.05$). Six months after treatment, 52.5% of patients (21/40) in the active group and 27.8% of patients (10/36) in the sham group presented an EHS>2 ($p<0.05$). At the same evaluation, 40.0% (16/40) and 13.9% (5/36) of patients had positive answers to GAQ-1, in the treated and sham groups, respectively ($p<0.05$). While this therapy is promising longer follow-up is needed that compares different ED etiologies and protocol characteristics.

In a randomized single-center controlled study conducted by Toussi, et al (2021), they are looked at 82 men post prostatectomy. with 6-month data available in 25 controls and 30 penile traction therapy cases. More penile traction therapy men reported satisfaction or improvement in penile length than controls. Adverse events were transient and mild; 87% would choose to repeat therapy, and 93% would recommend it to others. Although the use of the penile contracture device showed improvements in objective and subjective penile length post prostatectomy and measures of erectile dysfunction, intercourse satisfaction, external validation is warranted. Currently there is limited clinical trials, peer reviewed or supporting literature that supports the use of contracture devices for the treatment of Peyronie's Disease to aide with ED.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
37788	Penile revascularization, artery, with or without vein graft
37790 **(NMN)**	Penile venous occlusive procedure
54220	Irrigation of corpora cavernosa for priapism
54230	Injection procedure for corpora cavernosography
54231	Dynamic cavernosometry, including intracavernosal injection of vasoactive drugs (e.g., papaverine, phentolamine)
54235	Injection of corpora cavernosa with pharmacologic agent(s) (e.g., papaverine, phentolamine)
54240 **(NMN)**	Penile plethysmography
54250	Nocturnal penile tumescence and/or rigidity test

Code	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, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
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
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
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
55870	Electroejaculation
93980	Duplex scan of arterial inflow and venous outflow of penile vessels; complete study
93981	Duplex scan of arterial inflow and venous outflow of penile vessels; follow-up or limited study
0864T **(E/I)**	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy *(effective 01/01/24)*

HCPCS Codes

Code	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
J0270	Injection, alprostadil, per 1.25 mcg (Code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)
J0275	Alprostadil urethral suppository (Code may be used for Medicare when a drug administered under direct supervision of a physician, not for use when drug is self-administered)
J2440	Injection, papaverine HCL, up to 60 mg

Code	Description
J2760	Injection, phentolamine mesylate, up to 5 mg
L7900	Male vacuum erection system
L7902	Tension ring, for vacuum erection device, any type, replacement only, each
E0201 **(E/I)** Effective 04/01/25	Penile contracture device, manual, greater than 3 lbs traction force *(effective 04/01/25)*
S4988 **(E/I)** Termed 03/31/25	Penile contracture device, manual, greater than 3 lbs traction force

ICD10 Codes

Code	Description
E01.8	Other iodine-deficiency related thyroid disorders and allied conditions
E02	Subclinical iodine-deficiency hypothyroidism
E03.2-E03.9	Other hypothyroidism, other (code range)
E05.00-E05.91	Thyrotoxicosis [hyperthyroidism] (code range)
E10.40-E10.59; E10.69	Type 1 diabetes mellitus with complications (code range)
E11.40-E11.59; E11.69	Type 2 diabetes mellitus with complications (code range)
E13.40-E13.59; E13.69	Other specified diabetes mellitus with complications (code range)
E22.1-E23.7	Disorders of pituitary gland (code range)
E24.1	Nelson's syndrome
E27.0-E27.9	Other disorders of adrenal gland (code range)
E35	Disorders of endocrine glands in diseases classified elsewhere
E89.0	Postprocedural hypothyroidism
E89.3	Postprocedural hypopituitarism
E89.6	Postprocedural adrenocortical (-medullary) hypofunction
F52.0	Hypoactive sexual desire disorder
F52.21	Male erectile disorder
F52.32	Male orgasmic disorder
F52.8	Other sexual dysfunction not due to a substance or known physiological condition
N52.01 - N52.9	Male erectile dysfunction (code range)
R37	Sexual dysfunction, unspecified

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*Key Article

KEY WORDS

Caverject, Edex, ErecAid, Intracavernosal therapy, Intraurethral therapy, MUSE, Penile prosthesis, Penile vein ligation, Vacuum erection device, Vascular revascularization, Extracorporeal Shock Wave Therapy (ESWT)

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Vacuum Erection Devices (L34824). Please refer to the following LCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34824&ver=21&DocType=All&bc=AgIAAAAAIAAA&] accessed 09/25/24.

There is also a Local Coverage Article that addresses coding information for Vacuum Erection Devices (A52712) that may be accessed at: [https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52712&ver=25&LCDId=34824&DocType=All&bc=AgIAAAAAkAAA&=] accessed 09/25/24.