

SUBJECT: ERECTILE DYSFUNCTION

EFFECTIVE DATE: 09/16/99

**REVISED DATE: 09/19/01, 09/26/02, 10/23/03, 09/23/04,
10/27/05, 10/26/06, 10/24/07, 10/23/08**

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06/26/14**

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POLICY NUMBER: 7.01.30

CATEGORY: Miscellaneous

- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

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 are considered **medically appropriate** in patients with known erectile dysfunction with symptoms lasting more than 6 months. Treatment may be initiated prior to 6 months in cases of an acute event such as, penile trauma or radical pelvic surgery (e.g., prostatectomy or cystectomy), or drug-induced erectile dysfunction caused by treatment of a co-morbid condition.

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

A. Oral Drug Therapy:

Sildenafil citrate (Viagra), Vardenafil (Levitra), and Tadalafil (Cialis®) block the effect of an enzyme, Phosphodiesterase-5 (PDE5), causing an increase in penile blood flow necessary for an erection. Neither Viagra, Levitra, nor Cialis should be used in combination with other treatment modalities for erectile dysfunction. Viagra, Levitra and Cialis are contraindicated if the patient is actively taking nitrates in any form. Viagra, Levitra and Cialis should be used with caution in patients who take alpha-blockers. Levitra should be used with caution if a patient, or their family member, has a rare heart condition known as "prolongation of the QT interval". (Refer to Policy Guideline III regarding specific benefit information.)

B. Intracavernous Injection Therapy (e.g., Caverject, Edex):

Vasodilating agents such as papaverine, Phentamine, and/or prostaglandin E1 (alprostadil) are injected into the corpora of the penis to produce an erection. Patients using vasoactive drug injection therapy should be informed that a prolonged erection can occur and they should present for treatment if the erection lasts longer than 4 hours.

C. Transurethral Delivery System:

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

D. 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, resulting in an erection.

E. Penile Prosthetic Implants:

Three forms of penile prosthesis are available: semi-rigid, malleable and inflatable. Penile prosthetics are medically appropriate only in patients who fail or refuse other forms of therapy. Penile prosthesis implantation should not be performed in men with psychogenic erectile dysfunction unless a psychiatrist or psychologist participates in the preoperative evaluation and concurs with the need for prosthesis implantation.

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F. Arterial Revascularization:

This procedure 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. Arterial revascularization is only medically appropriate in men with normal corporeal venous function who have arteriogenic erectile dysfunction secondary to pelvic or perineal trauma.

G. Electroejaculation:

Electroejaculation (EE) 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. With vibratory and electrical stimulation along with appropriate methods of semen collection followed by intrauterine insemination, successful conception has resulted in a large number of cases. Electroejaculation is considered an appropriate alternative for men with spinal cord injury who desire to become biological fathers. It may also be indicated for the inability to ejaculate as a consequence of: retroperitoneal lymph node dissection (REPLND), insulin dependent diabetes, multiple sclerosis (MS), spina bifida or other neural tube deficits, complications due to bladder or rectal surgery, or idiopathic anejaculation (neurogenic, psychogenic or a combination of both).

II. 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 erectile dysfunction:

- topical medications containing vasodilators;
- arterial (penile) revascularization, except for the indication listed above;
- 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);
- Crural ligation for primary venous leakage ED; and
- Temporary or permanent lumbar ganglionic block or sympathectomy for ED secondary to cavernous adrenergic hypertone.

Diagnosis:

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

- Nocturnal penile tumescence (NPT) test only when the clinical evaluation is unable to distinguish psychogenic from organic impotence;
- Duplex scan in conjunction with intracorporeal papaverine;
- Pharmacological response test (PRT) using vasoactive medications such as papaverine HCL, prostaglandin E 1;
- Dynamic infusion cavernosonogram and cavernosometry for patients who meet the criteria for penile revascularization;
- Pudendal arteriography/angiography for patients who meet the criteria for penile revascularization;
- Penile biothesiometry (considered an integral part of the evaluation and management during an office visit).

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

- Dorsal nerve conduction latencies;
- Penile plethysmography;
- Cavernosal nerve mapping;
- Evoked potential measurements; and
- Corpora cavernosal electromyography.

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POLICY GUIDELINES:

- I. Prior authorization is contract dependent for all the following treatment modalities: vacuum constriction devices, penile prosthetic implants, and arterial revascularization. Vacuum constriction devices are considered to be durable medical equipment.
- II. The following treatment modalities are dependent upon a subscriber's contract with a prescription drug benefit: oral drug therapy, intracavernous injection therapy, and transurethral delivery system. *Refer to FLRx for information regarding coverage of oral drug therapy.*
- III. 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.

DESCRIPTION:

Erectile dysfunction (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.

Erectile dysfunction 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 as a result of a radical pelvic surgery (e.g., radical prostatectomy or cystectomy). Erectile dysfunction may also be a secondary symptom of systemic diseases or their 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 erectile dysfunction usually consists of a structured interview and a thorough physical examination. Adjunctive testing, such as a vascular assessment, neurological assessment and monitoring of nocturnal erections may be indicated in select patients.

Phase III clinical trials of alprostadil topical cream for the treatment of mild to severe erectile dysfunction (ED) have recently concluded. Topical alprostadil cream appears to improve ED in a broad range of patients and was safe & well tolerated in these trials, however, it has not received FDA approval for this use.

In 2005, New York State mandated that Medicaid, Family Health Plus, Healthy New York and standardized HMO and HMO/POS Direct Pay policies exclude coverage of drugs, procedures and supplies for the treatment of erectile dysfunction 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 which excludes coverage of drugs to treat erectile dysfunction for all Family Health Plus enrollees.

RATIONALE:

Sildenafil citrate (Viagra), Vardenafil (Levitra), Avanafil (Stendra) and Tadalafil (Cialis®) are phosphodiesterase type 5 inhibitors and are the only oral therapy approved by the FDA for the treatment of erectile dysfunction. Topical creams, gels or compounded injections containing vasodilators have not had studies provide evidence of their efficacy or safety for the treatment of men with erectile dysfunction and are not approved for this use by the FDA.

There is rarely any indication for the routine use of 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. The diagnostic use of 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.

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CODES: Number Description

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:	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 (eg, papaverine, phentolamine)
	54235	Injection of corpora cavernosa with pharmacologic agent(s) (eg, papaverine, phentolamine)
	54240 (NMN)	Penile plethysmography
	54250	Nocturnal penile tumescence and/or rigidity test
	54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
	54401	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

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93980 Duplex scan of arterial inflow and venous outflow of penile vessels; complete study
 93981 follow-up or limited study

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HCPCS: 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
 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

ICD9: 242.00-242.91 Thyrotoxicosis (code range)
 244.0-244.9 Acquired hypothyroidism (code range)
 250.00-250.93 Diabetes mellitus (code range)
 253.1-253.9 Pituitary dysfunction (code range)
 255.3-255.9 Adrenal dysfunction (code range)
 302.71 Psychosexual dysfunction with hypoactive sexual desire disorder
 302.72 Psychosexual dysfunction with inhibited sexual excitement (includes impotence)
 302.74 Male orgasmic disorder
 607.84 Impotence of organic origin

ICD10: 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)
 E10.11-E10.9 Type 1 diabetes mellitus with complications (code range)
 E11.00-E11.9 Type 2 diabetes mellitus with complications (code range)
 E13.00-E13.9 Other specified diabetes mellitus with complications (code range)
 E22.1-E23.7 Hyperfunction of pituitary gland (code range)
 E24.1 Nelson's syndrome
 E27.0-E27.9 Other disorders of adrenal gland (code range)

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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
F52.22	Female sexual arousal 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)

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KEY WORDS:

Caverject, Edex, ErecAid, Intracavernosal therapy, Intraurethral therapy, MUSE, Penile prosthesis, Penile vein ligation, Vacuum erection device, Vascular revascularization.

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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Erectile Dysfunction, Evaluation and Treatment.