

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	ERECTILE DYSFUNCTION
Policy Number	7.01.30
Category	Miscellaneous
Effective Date	10/18/01
Revised Date	09/26/02, 10/23/03, 09/23/04, 10/27/05, 10/26/06, 10/24/07, 10/23/08
Archived Date	10/28/09
Edited Date	06/24/10, 6/24/11, 06/28/12, 06/27/13, 06/26/14 , 06/25/15, 06/22/16, 08/25/17, 08/23/18, 08/22/19
Product Disclaimer	<ul style="list-style-type: none"> • 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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

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 (ED) 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®, Staxyn®), avanafil (Stendra®), and tadalafil (Cialis®) block the effect of an enzyme, phosphodiesterase-5 (PDE5), causing an increase in penile blood flow necessary for an erection.

1. PDE5 inhibitors should not be used in combination with other treatment modalities for erectile dysfunction.
2. PDE5 inhibitors are contraindicated if the patient is actively taking nitrates in any form.
3. PDE5 inhibitors should be used with caution in patients who take alpha-blockers.
4. Vardenafil 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 II 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.

Medical Policy: ERECTILE DYSFUNCTION

Policy Number: 7.01.30

Page: 2 of 6

- 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.
- 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:
- 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; and
 - E. 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:
- 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 E 1;
 - 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 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:
- A. Dorsal nerve conduction latencies;
 - B. Penile plethysmography;
 - C. Cavernosal nerve mapping;
 - D. Evoked potential measurements; and

Medical Policy: ERECTILE DYSFUNCTION

Policy Number: 7.01.30

Page: 3 of 6

E. Corpora cavernosal electromyography.

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

POLICY GUIDELINES

- I. 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 (Final Rule 2008), 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®, 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 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. Generic versions of Viagra, Cialis, and Levitra are currently available.

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.

Medical Policy: ERECTILE DYSFUNCTION**Policy Number: 7.01.30****Page: 4 of 6****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 (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
93980	Duplex scan of arterial inflow and venous outflow of penile vessels; complete study
93981	follow-up or limited study

Copyright © 2019 American Medical Association, Chicago, IL

Medical Policy: ERECTILE DYSFUNCTION**Policy Number: 7.01.30****Page: 5 of 6****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
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

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

Medical Policy: ERECTILE DYSFUNCTION

Policy Number: 7.01.30

Page: 6 of 6

REFERENCES

*Agency for Healthcare Research and Quality. Diagnosis and treatment of erectile dysfunction. Evidence Report/Technology Assessment 171. AHRQ Publication 08(09)-E016. 2009 May. [http://www.ahrq.gov/research/findings/evidence-based-reports/erecdys-evidence-report.pdf] accessed 7/8/19.

American Urological Association. Erectile Dysfunction: AUA Guideline (2018). [https://www.auanet.org/guidelines/erectile-dysfunction-(ed)-guideline] accessed 7/8/19.

BlueCross BlueShield Association. Erectile dysfunction – archived. Medical Policy Reference Manual. Policy #2.01.25. 2009 Oct 6.

Cai X, et al. The role of statins in erectile dysfunction: a systematic review and meta-analysis. Asian J Androl 2014 May-Jun;16(3):461-6.

Clavijo RI, Kohn TP, Kohn JR, Ramasamy R. Effects of Low-Intensity Extracorporeal Shockwave Therapy on Erectile Dysfunction: A Systematic Review and Meta-Analysis. J Sex Med. 2017 Jan;14(1):27-35. doi: 10.1016/j.jsxm.2016.11.001. Epub 2016 Dec 13.

Cui YS, et al. Avanafil for male erectile dysfunction: a systematic review and meta-analysis. Asian J Androl 2014 May-Jun;16(3):472-7.

Lu Z, Lin G, Reed-Maldonado A, Wang C, Lee YC, Lue TF. Low-intensity Extracorporeal Shock Wave Treatment Improves Erectile Function: A Systematic Review and Meta-analysis. Eur Urol. 2017 Feb;71(2):223-233. doi: 10.1016/j.eururo.2016.05.050. Epub 2016 Jun 16.

Mulcahy JJ, et al. Current use of penile implants in erectile dysfunction. Curr Urol Rep 2006 Nov;7(6):485-9.

New York State Insurance Department Regulation 62, Part 52, 36th Amendment (11NYCRR 52).

Zermann DH, et al. Penile prosthetic surgery in neurologically impaired patients: long-term follow-up. J Urol 2006 Mar;175(3 Pt 1):1041-4.

*Key Article

KEY WORDS

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

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Vacuum Erection Devices. Please refer to the following LCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34824&ver=11&DocType=All&bc=AgIAAAAAAAAAAAAA%3d%3d�>

There is also a Local Coverage Article that addresses coding information for Vacuum Erection Devices that may be accessed at: <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52712&ver=13&LCDId=34824&DocType=All&bc=AgIAAAAAGAAA&>