

MEDICAL POLICY



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 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
POLICY NUMBER: 7.01.30 CATEGORY: Miscellaneous	PAGE: 1 OF: 7
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>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.</i>	

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®), 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. Neither Viagra®, Levitra®, Stendra® nor Cialis® should be used in combination with other treatment modalities for erectile dysfunction.
2. Viagra®, Levitra®, Stendra® and Cialis® are contraindicated if the patient is actively taking nitrates in any form.
3. Viagra®, Levitra®, Stendra® and Cialis® should be used with caution in patients who take alpha-blockers.
4. 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 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 transurethraly 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.

<p>SUBJECT: ERECTILE DYSFUNCTION</p> <p>POLICY NUMBER: 7.01.30 CATEGORY: Miscellaneous</p>	<p>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 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 PAGE: 2 OF: 7</p>
--	--

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;

<p>SUBJECT: ERECTILE DYSFUNCTION</p> <p>POLICY NUMBER: 7.01.30 CATEGORY: Miscellaneous</p>	<p>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 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 PAGE: 3 OF: 7</p>
--	--

- D. Evoked potential measurements; and
- E. Corpora cavernosal electromyography.

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.
- IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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®), 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,

SUBJECT: ERECTILE DYSFUNCTION POLICY NUMBER: 7.01.30 CATEGORY: Miscellaneous	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 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 PAGE: 5 OF: 7
---	---

- 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 © 2018 American Medical Association, Chicago, IL

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

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)
- E35 Disorders of endocrine glands in diseases classified elsewhere
- E89.0 Postprocedural hypothyroidism
- E89.3 Postprocedural hypopituitarism
- E89.6 Postprocedural adrenocortical (-medullary) hypofunction

SUBJECT: ERECTILE DYSFUNCTION POLICY NUMBER: 7.01.30 CATEGORY: Miscellaneous	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 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 PAGE: 6 OF: 7
---	---

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)
R37	Sexual dysfunction, unspecified

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 7/20/17.
- American Urological Association. The management of erectile dysfunction: an update. 2007 Jun, reviewed and validity confirmed 2011 [[http://www.auanet.org/guidelines/erectile-dysfunction-\(2005-reviewed-and-validity-confirmed-2011\)](http://www.auanet.org/guidelines/erectile-dysfunction-(2005-reviewed-and-validity-confirmed-2011))] accessed 7/20/17.
- 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). [http://www.dfs.ny.gov/insurance/r_finala/2008/rf62a36t.pdf] accessed 7/20/17.
- 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 WORDS:

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

