



MASSACHUSETTS

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## Medical Policy

### Sexual Dysfunction Diagnosis and Therapy

#### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

#### Policy Number: 078

BCBSA Reference Number: 2.01.25; 2.01.46

NCD/LCD: N/A

#### Related Policies

- Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension, [#036](#)

#### Policy

##### **Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

The following tests in the diagnosis of erectile dysfunction may be considered **MEDICALLY NECESSARY**:

- Complete history and physical lab tests for hormones levels, and tests for pituitary thyroid, or adrenal dysfunction,
- Nocturnal penile tumescence tests (NPT) and rigidity monitoring, when psychogenic factor is suspected,
- Duplex scan (doppler and ultrasound) with intracorporal papaverine,
- Dynamic infusion cavernosogram and cavernosometry, and
- Prudendal arteriography.

The following medical treatments for erectile dysfunction may be considered **MEDICALLY NECESSARY**, with authorization for males over age 18 with a diagnosis of erectile dysfunction:

- Vacuum constriction devices, and
- Psychotherapy and behavioral therapy when appropriate, in accordance with each member's mentalhealth benefits.

The following medications for erectile dysfunction may be considered **MEDICALLY NECESSARY** for males over age 18 with a diagnosis of erectile dysfunction. Up to 4 units per 30 days for any combination of the following:

- Intracavernous vasoactive drug injection with papaverine, phentolamine, and/or prostaglandin E1 Caverject,® Edex® (Alprostadil)
- Muse® (Intraurethral insertion of prostaglandin E1)

- Viagra® (Sildenafil)
- Cialis® (Tadalafil)
- Levitra®, Staxyn™ (Vardenafil HCl) or
- Stendra™ (Avanafil).

The following medications are considered **NOT MEDICALLY NECESSARY** for males over age 18 as they are not FDA-approved for erectile dysfunction:

- Revatio™ (Sildenafil 20mg)
- Sildenafil 20mg.

**Note:** Coverage for Revatio™ is addressed in pharmacy [policy #036, Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension](#).

**Note:** Erectile dysfunction drugs are excluded from coverage for Medicare Advantage members. See Medicare section below.

FDA-approved external penile erection assistance devices may be considered **MEDICALLY NECESSARY** only for the following conditions:

- Severe diabetes mellitus with neuropathy,
- Peripheral vascular disease in the pelvis or extremity,
- Spinal cord injuries,
- Injuries to the genital or urinary tract,
- Venous insufficiency,
- Severe injuries to the bladder or pelvic nerves,
- Radical surgery of the genitals, lower urinary tract or rectum,
- Ambiguous genitalia or sex gender confusion at birth, and
- Patients receiving anti-androgen therapy for prostate disease.

Internal penile implants, may be considered **MEDICALLY NECESSARY** in males over age 18 with any of the following conditions, after other therapy has failed:

- Paraplegia,
- Peyronie's disease,
- After pelvic trauma with urinary system injury,
- After radiation therapy to the pelvis, or
- After radical pelvic or perineal surgery, including
  - Cystectomy,
  - Prostatectomy,
  - Partial penectomy,
  - Abdominal-perineal resection,
  - Anterior exenteration, and
  - Pelvic exenteration.

Internal penile implants for other organic diagnoses may be considered **MEDICALLY NECESSARY** only when documentation shows that impotence has existed for over one year, and other therapies, such as psychotherapy or sexual therapy when appropriate, have failed.

Penile arterial revascularization may be considered **MEDICALLY NECESSARY** for patients with normal corporeal venous function who have arteriogenic erectile dysfunction secondary to pelvic or perineal trauma.

The following tests for erectile dysfunction are **NOT MEDICALLY NECESSARY**, as these tests are of limited value in diagnosing erectile dysfunction:

- Dorsal nerve conduction latencies,
- Evoked potential measurements, and

- Corpora cavernosal electromyography (EMG).

The following medical treatments for erectile dysfunction are **NOT MEDICALLY NECESSARY**, as they have not been fully proven to improve health outcomes in patients with erectile dysfunction:

- Oral yohimbine therapy including but not limited to: Aphrodyne®, Testomar®, Vigorex®, Yocon®, and Dayto-Himbin®, because they are not FDA-approved for this purpose, and
- Topical creams, gels, or compounded injections containing vasodilators.

Penile implants or erection devices are **NOT MEDICALLY NECESSARY** for conditions other than those listed above.

Vacuum therapy for treatment of female sexual dysfunction (Eros Clitoral Therapy Device) is **NOT MEDICALLY NECESSARY**, because there is insufficient medical literature about the long-term effectiveness of this therapy.

Venous ligation in the treatment of venous leak impotency is **INVESTIGATIONAL**.

### **Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

Effective January 1, 2007, P.L. No. 109-91, section 103, amended section 1860D-2(e)(2)(A) of the **Act to exclude from the statutory definition of a Part D drug** "... a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration" (FDA). An erectile dysfunction (ED) drug meets the definition of a Part D drug when it is prescribed for medically accepted indications other than sexual or erectile dysfunction (such as pulmonary hypertension) for which the drug has been approved by FDA.

<http://www.oig.hhs.gov/oas/reports/region7/71003143.pdf>

### **Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required.

Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

	<b>Outpatient</b>
<b>Commercial Managed Care (HMO and POS)</b>	No
<b>Commercial PPO and Indemnity</b>	No
<b>Medicare HMO Blue<sup>SM</sup></b>	No
<b>Medicare PPO Blue<sup>SM</sup></b>	No

### **CPT Codes / HCPCS Codes / ICD Codes**

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

## CPT Codes

<b>CPT codes:</b>	<b>Code Description</b>
37788	Penile revascularization, artery, with or without vein graft
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)
54250	Nocturnal penile tumescence and/or rigidity test
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	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of 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
74445	Corpora cavernosography, radiological supervision and interpretation
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

## HCPCS Codes

<b>HCPCS codes:</b>	<b>Code Description</b>
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, noninflatable
J0270	Injection, alprostadil, 1.25 mcg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)
J0275	Alprostadil urethral suppository (code may be used for Medicare when drug administered under the 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
S0090	Sildenafil citrate, 25 mg
S0170	Anastrozole, oral, 1 mg

## Description

Sexual dysfunction describes any one of a group of sexual disorders characterized by inhibition either of sexual desire or the physiological changes that usually characterize sexual response. Sexual dysfunction disorders are generally classified into four categories: sexual desire disorders, sexual arousal disorders, orgasm disorders, and sexual pain disorders.

Male sexual dysfunction may reflect problems with the following factors: Libido, ejaculation, erectile function, or a combination of these factors. Erectile Dysfunction (ED), also known as impotence, is the inability to achieve and maintain penile erection and thus engage in sexual intercourse. This is a common, treatable condition affecting an estimated 18 million men in the United States alone. Male sexual dysfunction may be a result of one or more of the following conditions: medication side effects, endocrine disorders, peripheral vascular disease, neurological dysfunction, penile diseases, psychological disorders, and lifestyle factors. Once male sexual dysfunction is diagnosed, each of these potential causes must be carefully addressed prior to initiating treatment.

It is estimated that some 43% of American women experience female sexual dysfunction to some degree. Age may not be a significant factor, as women under 20 and over 50 experience problems with arousal, orgasm, and satisfaction. However, there is evidence that the majority of female sexual dysfunction happens after menopause when hormone production drops and vascular conditions are more common.

## Summary

Impotence is a failure of a body part 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.

All diagnostic and treatment options for sexual dysfunction are considered investigational except when used for the medically necessary indications that are consistent with the policy statement.

## Policy History

Date	Action
11/2016	Policy clarified that Revatio™ (Sildenafil 20mg) and Sildenafil 20mg are not covered as they are not FDA-approved for erectile dysfunction. 11/1/2016.
3/2016	Non-coverage of erectile dysfunction drugs clarified for Medicare Advantage members. 3/1/2016
9/2015	Clarified coding information.
7/2014	Updated to include Medications Staxyn™ and Stendra™.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
1/2010	BCBSA National medical policy review. Changes to policy statements.
6/2009	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
7/2008	BCBSA National medical policy review. Changes to policy statements.
6/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2007	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. FDA Talk Paper: [www.fda.gov/bbs/topics/ANSWERS/ANS01012.html](http://www.fda.gov/bbs/topics/ANSWERS/ANS01012.html).
2. Billups KL, Berman L, Berman J et al. a new non-pharmacological vacuum therapy for female sexual dysfunction. *J Sex Marital Ther* 2001; 27(5):435-41.
3. Wilson SK, Delk JR, Billups KL. Treating symptoms of female sexual arousal disorder with the Eros-Clitoral Therapy Device. *J Gend Specif Med* 2001; 4(2):54-8.
4. Billups KL. The role of mechanical devices in treating female sexual dysfunction and enhancing the female sexual response. *World J Urol* 2002; 20(2): 137-41.
5. Berman JR, Bassuk J. Physiology and pathophysiology of female sexual function and dysfunction. *World J Urol* 2002; 20(2):111-8.