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Medical Policy

Sexual Dysfunction Diagnosis and Therapy

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Policy Number: 078

BCBSA Reference Number: 2.01.25; 2.01.46 (For Plans internal use only)

Related Policies

Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension, #036

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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 <u>MEDICALLY NECESSARY</u>, 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 <u>MEDICALLY NECESSARY</u> 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 HCI) 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 <u>policy #036, Phosphodiesterase Type-5</u> <u>Inhibitors for Pulmonary Arterial Hypertension</u>.

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 <u>MEDICALLY</u> <u>NECESSARY</u> 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 <u>MEDICALLY NECESSARY</u> 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,
 - o Prostatectomy,
 - o Partial penectomy,
 - Abdominal-perineal resection,
 - o Anterior exenteration, and
 - o Pelvic exenteration.

Internal penile implants for other organic diagnoses may be considered <u>MEDICALLY NECESSARY</u> 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 <u>MEDICALLY NECESSARY</u> 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.

^{*} Up to 6 units per 30 days is allowed for generic Sildenafil. Up to 4 units per 30 days for brand name Viagra

- · 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**.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

| | Outpatient |
|---------------------------------------|--|
| Commercial Managed Care (HMO and POS) | Prior authorization is not required . |
| Commercial PPO and Indemnity | Prior authorization is not required . |

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 <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

| CPT codes: | Code Description |
|------------|--|
| 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

| HCPCS | |
|--------|--|
| codes: | Code Description |
| 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 |

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

| 0864T | Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low |
|-------|--|
| | energy |

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

| Fulley Hist | |
|-------------|---|
| Date | Action |
| 1/2024 | Clarified coding information. |
| 1/2023 | Medicare information removed. See MP #132 Medicare Advantage Management for |
| | local coverage determination and national coverage determination reference. |
| 10/2020 | Policy revised to indicate that up to 6 units per 30 days is allowed for generic Sildenafil. |
| | Brand name Viagra remains up to 4 units per 30 days. Effective 10/1/2020. |
| 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. |
| 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- | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No |
| 4/2012 | 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 | Annual review. Changes to policy statements. |
| 6/2009 | Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to |
| | policy statements. |
| 7/2008 | Annual 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.
- 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.