BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

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ERECTILE DYSFUNCTION TREATMENTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

ERECTILE DYSFUNCTION TREATMENTS (cont.)

Description:

Erectile dysfunction is the inability to consistently attain or sustain erection adequate for sexual penetration. In males, lack of sexual arousal is evidenced by erectile dysfunction, also called impotence.

Sexual Dysfunction:
The continual impairment of customary patterns of sexual interest and/or responses of an individual or a couple. Sexual dysfunction may result from organic diseases or conditions (e.g., Peyronie's disease, severe diabetes, vaginismus, vascular disease), trauma or surgery or it may be non-organic in nature (e.g., psychogenic).

Treatments for Erectile Dysfunction include:
- Arterial revascularization: bypasses penile blood flow blockage that has been caused by injury
- Enhanced external counterpulsation (EECP)
- Hand held devices e.g., vacuum constriction devices
- Prescription medications:
  - Sildenafil (Viagra®)
  - Vardenafil (Levitra®)
  - Tadalafil (Cialis®)
  - Avanafil (Stendra®)
  - Vardenafil HCL (Staxyn®)

- Intracavernous (within hollow spaces) injection of vasoactive drugs:
  - Alprostadil, Prostaglandin E_1 PGE_1 (Caverject®, Edex®)
  - Papaverine HCL
  - Regitine (Phentolamine)
  - Combination of papaverine HCL and phentolamine mesylate
  - Combination of papaverine HCL/phentolamine/prostaglandin

- Implantable devices
- Transurethral delivery of vasoactive drugs:
  - Alprostadil, Prostaglandin E_1 PGE_1 (MUSE®)

ERECTILE DYSFUNCTION TREATMENTS (cont.)

Criteria:

For enhanced external counterpulsation (EECP) for the treatment of erectile dysfunction, see BCBSAZ Medical Coverage Guideline #O262, "*Enhanced External Counterpulsation (EECP)*".

If benefit coverage for sexual dysfunction is available, requests for treatment for sexual dysfunction will be reviewed by the medical director(s) and/or clinical advisor(s).

COVERAGE FOR SEXUAL DYSFUNCTION IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER'S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

Non-Surgical Treatment:

- **If benefit coverage for organic sexual dysfunction is available**, the following treatments for erectile dysfunction are considered ***medically necessary***:

  1. Intracavernous injection of vasoactive drugs
  2. Transurethral delivery of vasoactive drugs
  3. Vacuum constriction devices

- **If benefit coverage for organic sexual dysfunction is available**, intracavernous injection of vasoactive drugs for preoperative testing of organic erectile dysfunction is considered ***medically necessary***.

Arterial Revascularization:

- **If benefit coverage for organic sexual dysfunction is available**, arterial revascularization for treatment of erectile dysfunction is considered ***medically necessary*** for males with normal corporeal venous function who have arteriogenic erectile dysfunction secondary to pelvic or perineal trauma.

ERECTILE DYSFUNCTION TREATMENTS (cont.)

Criteria: (cont.)

Implantable Penile Prosthesis:

- **If benefit coverage for organic sexual dysfunction is available**, implantable penile prosthesis for treatment of erectile dysfunction is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Erectile dysfunction is the result of **ONE** of the following to include, *but not limited to*:

     - Chronic, organic disease or condition
     - Trauma, e.g., severe spinal injury
     - Post-surgical complications, e.g., bladder surgeries, colorectal surgeries, prostate surgeries
     - Peyronie's disease of at least one (1) year duration and of such severity as to make coitus impossible

  2. Failure of the following conservative treatments, unless otherwise contraindicated:

     - Prescription medication (e.g., Viagra, Levitra, Cialis,Stendra,or Staxyn) **and**
     - Alternative treatment (e.g., vacuum erection devices, transurethral medications or intracavernous injection therapy)

  3. Impotency diagnosis as supported by the following:

     - Results of nocturnal penile tumescence test (NPT or sleep study) **and/or**
     - Positive treatment results of intracavernous injections of vasoactive drugs

ERECTILE DYSFUNCTION TREATMENTS (cont.)

Criteria: (cont.)

Implantable Penile Prosthesis: (cont.)

- **If benefit coverage for non-organic sexual dysfunction is available**, implantable penile prosthesis for treatment of "psychogenic" erectile dysfunction is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Severely debilitating impotence
  2. Impotence is irreversible despite psycho-behavioral therapeutic methods/interventions **and/or** medication regimen changes
  3. Failure of the following conservative treatments, unless otherwise contraindicated:

     - Prescription medication (e.g., Viagra, Levitra, Cialis, Stendra, or Staxyn) **and**
     - Alternative treatment (e.g., vacuum erection devices, transurethral medications or intracavernous injection therapy)

- **If benefit coverage for organic sexual dysfunction is available,** the following are considered ***not medically necessary*** in the diagnosis of erectile dysfunction:

  1. Dorsal nerve conduction latencies
  2. Evoked potential measurements
  3. Corpora cavernosal electromyography

- **If benefit coverage for organic sexual dysfunction is available, the following indications are** considered ***experimental or investigational*** in the treatment of erectile dysfunction based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

  These indications include, *but are not limited to:*

  - Arterial revascularization except as listed above
  - Venous ligation in the treatment of venous leak impotency

ERECTILE DYSFUNCTION TREATMENTS (cont.)

Resources:

Literature reviewed 04/12/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 04/16/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.01.25 BCBS Association Medical Policy Reference Manual. Erectile Dysfunction. Re-issue date 10/06/2009, issue date 05/30/1997.

2. Babaev A, Jhaveri RR. Angiography and endovascular revascularization of pudendal artery atherosclerotic disease in patients with medically refractory erectile dysfunction. *J Invasive Cardiol.* May 2012;24(5):236-240.

3. Flores S, Tal R, O'Brien K, Mulhall JP. Outcomes of crural ligation surgery for isolated crural venous leak. *J Sex Med.* Dec 2011;8(12):3495-3499.

4. Giuliano F, Rowland DL. Standard operating procedures for neurophysiologic assessment of male sexual dysfunction. *J Sex Med.* May 2013;10(5):1205-1211.

5. Glina S, Ghanem H. SOP: corpus cavernosum assessment (cavernosography/cavernosometry). *J Sex Med.* Jan 2013;10(1):111-114.

6. Rogers JH, Goldstein I, Kandzari DE, et al. Zotarolimus-eluting peripheral stents for the treatment of erectile dysfunction in subjects with suboptimal response to phosphodiesterase-5 inhibitors. *J Am Coll Cardiol.* Dec 25 2012;60(25):2618-2627.

7. Rogers JH, Rocha-Singh KJ. Endovascular therapy for vasculogenic erectile dysfunction. *Curr Treat Options Cardiovasc Med.* Apr 2012;14(2):193-202.

8. Sohn M, Hatzinger M, Goldstein I, Krishnamurti S. Standard operating procedures for vascular surgery in erectile dysfunction: revascularization and venous procedures. *J Sex Med.* Jan 2013;10(1):172-179.

ERECTILE DYSFUNCTION TREATMENTS (cont.)

Resources: (cont.)

9. UpToDate Authors Glenn R Cunningham MD. Evaluation of male sexual dysfunction. 12/16/2015.

10. Virseda-Chamorro M, Lopez-Garcia-Moreno AM, Salinas-Casado J, Esteban-Fuertes M. Usefulness of electromyography of the cavernous corpora (CC EMG) in the diagnosis of arterial erectile dysfunction. *Int J Impot Res.* Jul-Aug 2012;24(4):165-169.

11. Von Allmen RS, Nguyen DP, Birkhauser FD, et al. Lesion Pattern in Patients With Erectile Dysfunction of Suspected Arterial Origin: An Angiographic Study. *Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists.* Feb 2016;23(1):76-82.

FDA Summary Statements for Device, External penile rigidity. Device names include, *but are not limited to*:

Reliant Charger

- FDA-approved indication: To cause engorgement of the penis for men who are having difficulty with organic or psychological impotence.

FDA Summary Statement for Device, External penile rigidity. Device names include, *but are not limited to:*

ErecAid® Classic System
ErecAid® Esteem Manual System
ErecAid® Esteem Battery System

- FDA-approved indication: To artificially produce an erection in males suffering from erectile dysfunction (impotence) in order to facilitate sexual intercourse. A vacuum is applied to the penis, causing it to become erect and rigid as blood is drawn into the corpora cavernosa. A constriction ring is then placed on the base of the penis to restrict venous blood flow out of the penis. The device is intended to be used at home or in a doctor's office or clinic.

FDA Summary Statement for Device, External penile rigidity. Device names include, *but are not limited to:*

Rapport V.T.D.

- FDA-approved indication: To achieve a penile erection for males suffering from erectile dysfunction.