

## OHCA Guideline

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| <b>Medical Procedure Class:</b>  |   | <b>Penile Implants</b>                                 |
| Initial Implementation Date:   |   | 5/26/2021  |
| Last Review Date:  |   | 5/25/2021  |
| Effective Date:  |   | 5/26/2021  |
| Next Review/Revision Date:   |   | May 2024   |
| * This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect, or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.   |   |  |
| <input checked="" type="checkbox"/> New Criteria   |   | <input type="checkbox"/> Revision of Existing Criteria |
| <b>Summary</b>   |   |  |
| <b>Purpose:</b>  | To provide guidelines to assure medical necessity and consistency in the prior authorization process. |  |
| <b>Definitions</b>   |   |  |
| Erectile dysfunction - the consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual satisfaction, including satisfactory sexual performance   |   |  |
| <b>Description</b>   |   |  |
| Penile prosthesis implantation is a treatment option for men with ED who have failed less invasive treatments. The U.S. Food and Drug Administration (FDA) considers the rigid penile implant as a Class II device. The semi-rigid rods are implanted into the corpora cavernosa of the penis to provide rigidity. Inflatable penile implants are considered Class III devices by the FDA. Inflatable cylinders are implanted in the penis and are connected to a reservoir filled with fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. Penile rigidity is achieved when the cylinders are filled with fluid.   |   |  |
| <b>CPT Codes Covered Requiring Prior Authorization (PA)</b>  |   |  |
| 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417 (see CPT manual for description of codes)   |   |  |
| <b>Approval Criteria</b>   |   |  |
| Penile implants are considered medically necessary when <b><u>ALL</u></b> the following criteria are met:<br>1. The history and physical exam of the member are consistent with sexual dysfunction; <b><u>AND</u></b><br>2. The member has a medical (organic) condition that directly contributes to the sexual dysfunction, including one or more of the following:<br>a. Arterial disease (e.g., atherosclerosis); <b>or</b><br>b. Diabetes; <b>or</b><br>c. Neurogenic disease (e.g., stroke, multiple sclerosis, spinal cord injuries, etc.); <b>or</b><br>d. Prostate disease (e.g., Peyronie's disease); <b>or</b><br>e. After pelvic trauma with urinary system injury; <b>or</b><br>f. After radiation therapy to the pelvis; <b>or</b><br>g. After radical pelvic or perineal surgery; <b><u>AND</u></b><br>3. Member has continued erectile dysfunction after phosphodiesterase type 5 inhibitor (PDE5) pharmacotherapy (sildenafil, vardenafil, tadalafil, and avanafil), or pharmacotherapy contraindicated or not tolerated: <b><u>AND</u></b> |   |  |

4. Alternative treatments have been tried and failed, such as vacuum erection devices, intraurethral medications, or intracavernous injection.

Removal of a penile implant is considered medically necessary when the following criteria is met:

1. If the device malfunctions, breaks, or becomes infected

Removal and replacement of a penile implant is considered medically necessary when the following criteria are met:

1. If the device malfunctions, breaks, or becomes infected; **AND**
2. If the medical necessity criteria continue to be met; **AND**
3. If replacement is not part of the manufacturer warranty.

### **Contraindications**

Implantation of a penile prosthesis is contraindicated in the presence of infection (e.g., systematic, pulmonary, urinary tract, cutaneous). The penis and scrotum must be free of any dermatitis, wounds, or other cutaneous lesions.

### **References**

1. OHCA Policy and Procedures, OAC 317:30-3-1 (f)
2. CMS NCD for Diagnosis and Treatment of Impotence 230.4 Version 1.
3. Burnett AL, Nehra A, Breau RH et al: Erectile dysfunction: AUA guideline. J Urol 2018; 200: 633. [https://www.auanet.org/guidelines/guidelines/erectile-dysfunction-\(ed\)-guideline](https://www.auanet.org/guidelines/guidelines/erectile-dysfunction-(ed)-guideline) accessed 05/25/2021
4. UpToDate; Surgical Treatment of Erectile Dysfunction; Stephen Lazarou, MD; April 2021
5. InterQual 2021; April 2021 Release, CP: Procedures – Penile Implant Insertion
6. BCBS Massachusetts, Sexual Dysfunction Diagnosis and Therapy, Policy number 078, October 2020.