



## Medical Policy Manual Draft New Policy: Do Not Implement

### Treatment for Sexual Dysfunction in Males: Non-pharmacologic

### **DESCRIPTION**

Erectile dysfunction (ED) affects at least 12 million men in the United States and can be caused by vascular, neurologic, psychological or hormonal factors. Hypertension, diabetes, hyperlipidemia, obesity, testosterone deficiency and prostate cancer treatment are all common conditions related to ED. Common psychological issues are performance anxiety and relationship issues and can possibly be resolved with psychotherapy and/or behavioral therapy. Medication and substance use (i.e., antidepressants, tobacco use) can cause or exacerbate ED. Lifestyle changes, such as, tobacco cessation, regular exercise, weight loss, improved control of diabetes, hyperlipidemia and hypertension are recommended as initial interventions. Men with ED should have a complete medical, sexual, and psychosocial history done along with a physical exam and any labs needed. The first line of treatment is oral phosphodiesterase-5 inhibitors. Second-line treatment includes vacuum devices and alprostadil. When these treatments are ineffective, penile prosthesis are then an option.

### **POLICY**

- Penile prosthesis is considered medically necessary if the medical appropriateness criteria are met. (See Medical Appropriateness below.)
- Removal of penile prosthesis is considered *medically necessary* if the medical appropriateness criteria are met. (See Medical Appropriateness below.)
- Treatment for erectile dysfunction with any of the following is considered investigational:
  - Extracorporeal shock wave therapy (ESWT)
  - Platelet-rich plasma therapy
  - Intracavernosal stem cell therapy

### **MEDICAL APPROPRIATENESS**

- Penile prosthesis is considered medically appropriate if ALL of the following are met:
  - Lifestyle modifications (e.g., weight management, quit smoking, sedentary lifestyle) have been tried and failed
  - Medication changes if needed (e.g., antihypertensive drugs, antihistamines, antidepressants, tranquilizers, histamine-receptor antagonist)
  - Complete history and physical exam and ANY ONE of the following:
    - All related conditions that may cause ED has been ruled out using labs or other necessary test. (e.g., cardiovascular disease, diabetes, hyperlipidemia, hypertension, peyronie's disease, endocrine disorders, metabolic syndrome, Neurologic conditions)
    - Optimized medical management of any condition that may cause ED (e.g., cardiovascular disease, diabetes, hyperlipidemia, hypertension, peyronie's disease, endocrine disorders, metabolic syndrome, Neurologic conditions)
  - Oral phosphodiesterase-5 inhibitors (e.g., avanafil, tadalafil), if not contraindicated, have been tried and failed





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- o Intraurethral medication, Intracavernosal injection (caverject), vacuum device has been tried and failed
- Absence of ALL the following:
  - Systemic infection
  - Cutaneous infection
  - Urinary tract infection
- Removal of a penile prosthesis is medically appropriate for ANY of the following:
  - Infection
  - Mechanical failure
  - Urinary obstruction
  - Intractable pain

#### IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only.
  It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

### **ADDITIONAL INFORMATION**

Restorative therapies have emerged as a less invasive treatment option for ED more high-quality studies with long-term follow-up outcomes are needed to evaluate efficacy, reproducibility, and define evidenced-based protocols to standardize techniques.

### **SOURCES**

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Centers for Medicare & Medicaid Services. Palmetto GBA. CMS.gov. NCD for Diagnosis and Treatment of Impotence. (230.4). Retrieved May 29, 2025 from <a href="http://www.cms.gov">http://www.cms.gov</a>.

Chung, D.Y., Ryu, J-K., & Yin, G.N. (2023). Regenerative therapies as a potential treatment of erectile dysfunction. *Investigative and Clinical Urology*, 64 (4), 312-324. (Level 3 evidence)

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Mesquita, F.C., Barros, R., Lima, T.F.N., Velasquez, D., Favorito, L.A., Pozzie, E., et al. (2024). Evidence of restorative therapies in the treatment of peyronie disease: a narrative review. *Official Journal of the Brazilian Society of Urology*, 50 (6), 703-713. (Level 4 evidence)

Mykoniatis, I., Pyrgidis, N., Sokolakis, I., Ouranidis, A., Sountoudlides, P., Haidich, A., et al. (2021). Assessment of combination therapies vs monotherapy for erectile dysfunction a systematic review and meta-analysis. *JAMA Network Open*, 4 (2), e2036337. Doi: 10.1001. (Level 1 evidence)

Wang, X., Liu, H., Tang, H., Wu, G., Chu, Y., Wu, J., et al. (2024). Updated recommendations on the therapeutic role of extracorporeal shock wave therapy for peyronie's disease: systematic review and meta-analysis. *BMC Urology, 23 (1),* 145. (Level 1 evidence)

EFFECTIVE DATE	
x/x/2025	(x/x/25 – Approved by MTAC; New policy requested by Commercial UM due to MCG guideline being so vague and more plans are starting to cover this device

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