



MEDICAL POLICY STATEMENT

Ohio Medicaid

Policy Name & Number	Date Effective
Penile Implants in the Treatment of Erectile Dysfunction-OH MCD-MM-0033	11/01/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject**Penile Implants in the Treatment of Erectile Dysfunction****B. Background**

Erectile Dysfunction (ED) is the consistent or recurrent inability to acquire or sustain an erection, and the most common sexual problem affecting males. Surveys suggest 5-10 percent of men between the ages of 20 and 30 are affected with that number increasing to 35-40 percent of men aged 70 or older. The National Institutes of Health (NIH) estimates that up to 30 million men experience erectile dysfunction.

Various treatment modalities exist for ED. One treatment option is a surgical penile implant (also called a penile prosthesis). A penile implant is indicated when there is a clear medical cause for ED and when the problem is unlikely to resolve or improve naturally or with other medical treatments. A basic penile prosthesis consists of a pair of bendable, silicone rods that are surgically implanted within the erection chambers of the penis. Identification of the underlying etiology is an important first step. This includes ruling out the adverse effects of medication(s), identifying and treating risk factors.

C. Definitions

- **Erectile Dysfunction** – The consistent or recurrent inability to acquire or sustain an erection.
- **Neurogenic Impotence** – Nervous system issues affecting the ability to maintain or have an erection.
- **Vascular Impotence** – Restricted/Decreased blood flow to the penis causing impotence.

D. Policy**I. Medication is the first line of treatment for ED:**

- A. Oral phosphodiesterase type 5 inhibitors
- B. Intra-urethral alprostadil
- C. Intracavernous vasoactive drug injections.

Ohio Medicaid does not cover medications including oral, injectable, and transdermal varieties for the treatment of erectile dysfunction.

II. External penile pumps or vacuum constriction devices (VCD) are the second line of treatment after first line therapy has failed.

Ohio Medicaid does not cover external penile pumps and vacuum constriction devices.

III. Internal penile prosthetic implants are covered in extraordinary circumstances. They are considered medically necessary when the following conditions are met:

- A. First and second line therapy has been documented ineffective, or there is a compelling, well documented reason to proceed with surgery without a failed trial of first and second line therapies.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

- B. Absence of active alcohol or substance use disorder as documented in the medical record.
- C. Absence of drug induced impotence related to **ALL** of the following:
 - 1. Anabolic steroid use
 - 2. Anticholinergics
 - 3. Antidepressants
 - 4. Antipsychotics or central nervous system depressants.
- D. Neurogenic impotence due to **ONE** of the following:
 - 1. Diabetes
 - 2. Fractured Pelvis
 - 3. Major surgery of the pelvis, retroperitoneum, radical prostatectomy, or colorectal surgery
 - 4. Multiple sclerosis
 - 5. Spina bifida
 - 6. Spinal cord injury/disease
 - 7. Syringomyelia.
- OR**
- E. Vascular Impotence due to **ONE** of the following:
 - 1. Hypertension
 - 2. Intrapenile arterial disease
 - 3. Penile Fracture
 - 4. Peyronies Disease
 - 5. Smoking
 - 6. Status post cavernosal infection
 - 7. Impotence due to radiation therapy to the pelvis or retroperitoneum.
- IV. Internal penile prosthetic implant removal is considered medically necessary when **ANY** of the following are met:
 - A. Infection
 - B. Mechanical failure
 - C. Urinary Obstruction
 - D. Intractable Pain.

E. Conditions of Coverage
N/A

F. Related Policies/Rules
N/A

G. Review/Revision History

DATE		ACTION
Date Issued	07/26/2016	
Date Revised	05/13/2020	Updated References, Updated Background information, condensed medical criteria.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

	05/11/2022	Added penile implant information to Background; updated references.
	05/10/2023	No changes. Updated references. Approved at Committee.
Date Effective	11/01/2023	
Date Archived		

H. References

1. American Urological Association. Erectile Dysfunction (ED) Guideline. (2018). Retrieved April 20, 2023 from www.auanet.org.
2. Cunningham G. Treatment of Male Sexual Dysfunction (2015). UpToDate. Retrieved April 20, 2023 from www.uptodate.com.
3. Lazarou S. Surgical Treatment of Erectile Dysfunction (2015). UpToDate. Retrieved April 20, 2023 from www.uptodate.com.
4. MCG. 27th ed. (2023) GRG - SG-US (ISC GRG)- Urologic Surgery or Procedure GRG. Retrieved April 20, 2023 from www.careweb.careguidelines.com.
5. Ohio Administrative Code 5160-9-03. Erectile Dysfunction Medications (2016, January). Retrieved April 20, 2023 from www.codes.gov/oac.

Independent medical review – 05/2020

Approved by ODM on 08/10/2023.