



MEDICAL POLICY STATEMENT

Ohio Medicaid

Policy Name & Number	Date Effective
Penile Implants in the Treatment of Erectile Dysfunction OH MCD-MM-0033	09/01/2022-10/31/2023
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.

Table of Contents

A. Subject.....	2
B. Background.....	2
C. Definitions	2
D. Policy	2
E. Conditions of Coverage-N/A.....	3
F. Related Policies/Rules-N/A	3
G. Review/Revision History.....	3
H. References.....	4

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. ED is the most common sexual problem effecting males. Surveys suggest 5-10 percent of men between the age of 20 and 30 and are affected; the number increases to 35-40 percent of men in the 70s. The NIH estimates that up to 30 million suffer from erectile dysfunction.

A surgical penile implant (also called a penile prosthesis) is a treatment option for men with erectile dysfunction (ED). The simplest type of prosthesis consists of a pair of bendable, silicone rods surgically implanted within the erection chambers of the penis. A penile implant is usually used 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.

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. Three lines of therapeutic options are listed below.

C. Definitions

- **Erectile Dysfunction** – “ED” is the consistent or recurrent inability to acquire or sustain an erection.
- **Neurogenic Impotence**-Nervous system issues is affecting the ability to maintain or have an erection.
- **Vascular Impotence**- Blood flow to the penis is causing the impotence.

D. Policy

I. First line treatment of ED is considered Medication

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

NOTE: Medications including oral, injectable, and transdermal for the treatment of erectile dysfunction are not a covered benefit though Ohio Medicaid.

II. Second line treatment of ED is external penile pumps or vacuum constriction devices (VCD) used after first line therapy has failed.

NOTE: External penile pumps and vacuum constriction devices are not a covered benefit through Ohio Medicaid.

III. Internal Penile Prosthetic Implants are covered in extraordinary circumstances, they are considered medically necessary when the following 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.

- 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 the following is 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.
	05/11/2022	Added penile implant information to Background; updated references

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

Date Effective	09/01/2022	
Date Archived	10/31/2023	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Lawriter-OAC-5160-9-03 Erectile Dysfunction Medications (2016, January). Retrieved 04/15/2022 from www.codes.gov/oac
2. Erectile dysfunction (ED) guideline - American Urological Association. (2018). Retrieved 04/15/2021 from <https://www.auanet.org>.
3. Lazarou, S. Surgical Treatment of Erectile Dysfunction (2015) Retrieved 04/15/2022 UpToDate.
4. Cunningham, G. Treatment of Male Sexual Dysfunction (2015) Retrieved 04/15/2022. UpToDate.

Independent medical review – 05/2020