

SEXUAL DYSFUNCTION AND IMPOTENCE

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5/20, 5/21, 5/22, 8/22, 8/23, 8/24, 8/25

Date Of Origin: July 16, 1990 Status: Current

Summary of Changes

Changes:

• For Medicaid members: Penile Implant Insertion is medically necessary when InterQual criteria are met.

Additions:

• New sections: Government Regulations, and Guidelines/Position Statements.

Deletion:

• I.C.1.a.i: Removed "effective 1/1/2023"

I. POLICY/CRITERIA

- A. Evaluation of impotence is covered as a medical service.
 - 1. Appropriate diagnostic tests for impotence include tests to:
 - a. Determine if the cause of impotency is organic or non-organic.
 - b. Measure blood pressure and blood flow in the penis.
 - c. Evaluate the condition of blood vessels leading to the penis.
 - d. Determine if the nerve supply to the penis is adequate.
- B. Treatment with insertion of a penile prosthesis is covered as a medical service.
 - 1. Penile prosthesis implantation.
 - a. Medicaid members: May be medically necessary if InterQual criteria (Penile Implant Insertion) are met.
 - b. Coverage is provided for only one penile prosthesis implantation per member lifetime.
- C. Treatment with drugs is not a covered benefit unless the member's contract has a rider for coverage.
 - 1. Drug Therapy (oral, injectable, pellets):
 - a. Drug therapy is not a covered benefit unless:
 - i. The drug is covered as standard on a Priority Health formulary that applies to the member, OR
 - ii. The Sexual Dysfunction Rider is a part of the member's contract.
 - 2. Medicaid members: Drug therapy is not a covered benefit as governed by State and Federal regulations.
- D. The treatment of impotence with equipment is covered at the Durable Medical Equipment (DME) benefit level.



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- 1. External Penile Erectile Vacuum Devices:
 - a. External penile erectile vacuum devices are covered at the Durable Medical Equipment benefit level. Coverage requirements include:
 - i. Member at least 18 years of age with a diagnosis of organic erectile dysfunction (ED).
 - ii. An appropriate evaluation must be done to determine the necessity for the external penile vacuum pump. This would include, but is not limited to:
 - o Medical, psychosocial and sexual history;
 - o Physical examination; and
 - Laboratory and diagnostic evaluation. The laboratory testing should be thorough enough to identify comorbid conditions that may predispose the member to ED and that may contraindicate certain therapies. The effect of the member's other medications on ED should also be considered.
 - iii. Member has the manual dexterity to utilize the device.
 - iv. Adequate penile blood supply is present.
 - v. Devices are most effective in partial impotence.
 - vi. Contraindicated in patients with blood dyscrasias, including sickle cell disease, or those taking anticoagulants. Coverage is provided for only one external penile vacuum pump per member lifetime under the DME benefit.
- 2. Clitoral therapy devices (e.g., Eros) are covered under the Medical Supply or Durable Medical Equipment (DME) benefit. Priority Health will provide coverage if there is a documented underlying disease/condition.
 - a. Indications for use of the Eros device include:
 - i. Greater clitoral and genital engorgement
 - ii. Increased vaginal lubrication
 - iii. Enhanced ability to achieve orgasm
 - iv. Improved overall sexual satisfaction
 - b. Clitoral therapy devices are **NOT** a covered benefit for Medicaid members.
- E. Coverage is not provided for:
 - a. Psychological counseling for ED
 - b. Exogenous testosterone replacement therapy given solely for ED
 - c. Extracorporeal shock wave therapy for Peyronie's disease
 - d. Stem Cell Therapy for erectile dysfunction is experimental and investigational and is not a covered benefit.

II. GOVERNMENT REGULATIONS

CMS Coverage Determinations	Title and Number
National Coverage Determinations	Diagnosis and Treatment of Impotence,
(NCDs)	NCD 230.4



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Local Coverage Determinations	N/A
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III. GUIDELINES/POSITION STATEMENTS

Medical or Professional Society	Recommendation
American College of Obstetricians and Gynecologists	Female Sexual Dysfunction, Practice Bulletin Number 213, July 2019
Gynecologists	Bulletin Number 213, July 2017
American Urological Association (AUA)	Erectile Dysfunction: AUA Guideline
	(2018)

IV. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the <u>Priority Health Provider Manual</u>.

V. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ HMO/EPO: This policy applies to insured HMO/EPO plans.
- ❖ POS: This policy applies to insured POS plans.
- * PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- ❖ INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- * MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945-42543-42546-42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945-5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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VI. DESCRIPTION

Erectile dysfunction (ED) is defined as the consistent or recurrent inability of a man to attain and maintain an erection sufficient for sexual intercourse (McCabe, 2016). ED may be organic in nature, that is, caused by a detectable physiological or structural change. A medication review is imperative during the assessment period, since ED cases may be caused by medications, including over-the counter preparations. The likelihood of erectile dysfunction increases with age but is not an inevitable consequence of aging.

Likely causes of male erectile dysfunction, based on clinical presentation, are listed in Appendix A. Treatment will vary depending on the severity and cause of the dysfunction. In the case of uncomplicated ED, treatment usually consists of oral medication known as phosphodiesterase-5 inhibitors (PDE-5). PDE-5 agents are more commonly known as Viagra (sidenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) and are generally considered safe and effective.

For men who do not respond to these oral medications, injectable drugs are available for treatment. Alprostadil, papaverine and phentolamine are drugs that are injected into the corpus cavernosa. These drugs require titration and are initially injected by the physician. Self-injection will ultimately occur after titration has been achieved. Two of these drugs, alprostadil and papaverine, can also be administered through a small catheter into the urethra.

Oral testosterone can reduce ED in some men with low levels of natural testosterone, but it is often ineffective. Studies indicate that although testosterone deficiency may affect the libido, it does not necessarily affect the ability to have erections. Yohimbine hydrochloride and its derivatives Aphrodyne, Testomar, Vigorex, Yocon, and Dayto-Himbin are not FDA approved for this purpose. Other oral drugs, such as dopamine, serotonin agonists, and trazodone, have not been proven to be effective. The results of scientific studies to substantiate these claims have been inconsistent. Despite the fact that herbal remedies are popular worldwide in the treatment of ED, the mechanisms of action, effectiveness, and safety of these agents is questionable. Even the product potency and quality within a given brand may be inconsistent. For men who cannot or do not wish to use drug therapy, an external vacuum device may be an appropriate treatment option. With proper instruction 75% of men can achieve a functional erection.

For more severe disease, usually associated with advanced diabetes, surgical or radiation treatment for prostate or bladder cancer or Peyronie's disease, drug treatment or treatment with an external vacuum device may be ineffective. Implantation of a penile prosthesis is a therapeutic alternative. There are three basic kinds of penile implants: semi-rigid (malleable) implant, two-piece inflatable implant, and three-piece inflatable implant.

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Female sexual dysfunction (FSD) can be caused by diabetes, pelvic trauma, hypertension, vascular disease, menopause, or may be idiopathic. Eros clitoral stimulation device is used to obtain greater clitoral engorgement and enhance the ability to achieve an orgasm.

V. CODING INFORMATION

ICD-10 Codes that ma	y apply:
E10.40 - E10.43	Type 1 diabetes mellitus with neurological complications
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.69	Type 1 diabetes mellitus with other specified complication
E11.40 - E11.43	Type 2 diabetes mellitus with neurological complications
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
E13.40 - E13.43	Other specified diabetes mellitus with neurological complications
E13.49	Other specified diabetes mellitus with other diabetic neurological
	complication
I73.9	Peripheral vascular disease, unspecified
N50.1	Vascular disorders of male genital organs
N52.01 – N52.9	Male erectile dysfunction
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
N94.9	Unspecified condition associated with female genital organs and menstrual cycle
N95.8	Other specified menopausal and perimenopausal disorders
N95.9	Unspecified menopausal and perimenopausal disorders
Q52.6	Congenital malformation of clitoris
Q52.8	Other specified congenital malformations of female genitalia
Q52.9	Congenital malformation of female genitalia, unspecified
R10.2	Pelvic and perineal pain
R39.9	Unspecified symptoms and signs involving the genitourinary system
S38.001A - S38.03xS	Crushing injury of external genital organs
S39.840A – S39.848S	Other specified injuries of external genitals
S39.94xA - S39.94xS	Unspecified injury of external genitals

CPT/HCPCS Codes:

CP1/HC	PCS Codes:
Diagnost	<u>ic</u>
51792	Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)
54230	Injection procedure for corpora cavernosography
54231	Dynamic cavernosometry, including intracavernosal injection of vasoactive drugs (e.g., papaverine, phentolamine)
54235	Injection of corpora cavernosa with pharmacologic agent(s) (e.g., papaverine, phentolamine)
J2440*	Injection, papaverine HCl, up to 60 mg



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J2760*	Injection, phentolamine mesylate, up to 5 mg
J0270*	Injection, alprostadil, 1.25 mcg (code may be used for Medicare when drug
30270	administered under direct supervision of a physician, not for use when drug is self-
	administered ander direct supervision of a physician, not for use when drug is sen-
J0275*	Alprostadil urethral suppository (code may be used for Medicare when drug
30273	administered under direct supervision of a physician, not for use when drug is self-
	administered under direct supervision of a physician, not for use when drug is sen-
* Not ac	wered as a medical drug for these indications for Medicaid or Medicare
NOI CO	vereu as a medical arag for these indications for Medicala or Medicare
54240	Penile plethysmography
54250	Nocturnal penile tumescence and/or rigidity test (Not Covered for Medicaid)
3 1230	140cturnal points turnescence and of rigidity test (1401 Covercu for interieuru)
74445	Corpora cavernosography, radiological supervision and interpretation
7 1 1 1 3	Corpora cavernosography, radiological supervision and interpretation
93980	Duplex scan of arterial inflow and venous outflow of penile vessels; complete study
93981	Duplex scan of arterial inflow and venous outflow of penile vessels; follow-up or
75701	limited study
	ininica stady
Surgical	Treatments (Authorization required for Medicaid members only)
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of
21102	pump, cylinders, and reservoir
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile
51110	prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile
5	prosthesis through an infected field at the same operative session, including irrigation
	and debridement of infected tissue
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained)
31110	penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained)
31117	penile prosthesis through an infected field at the same operative session, including
	irrigation and debridement of infected tissue
	inigution and debridement of infected tissue
(No auth	orization required):
54406	Removal of all components of a multi-component, inflatable penile prosthesis without
	replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis,
5 1 115	without replacement of prosthesis
	Time at replacement of prosinesis
Devices	
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
L7900	Male vacuum erection system (Not covered for Medicaid or Medicare)
E1399	Durable medical equipment, miscellaneous (for Eros device)
21377	(Explanatory notes must accompany claims billed with unlisted codes.)
	(2. promiser) y notes must accompany ciams onica wint antisted codes.)



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0864T Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy

ICD-10 Codes that are not covered for Behavioral Health or medical services:

F52.0 – F52.9 Sexual dysfunction not due to a substance or known physiological

condition

R37 Sexual dysfunction, unspecified

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APPENDIX A

Likely Causes of Male Erectile Dysfunction Based on Clinical Presentation (This is not an all-inclusive list):

Psychological Causes

- Young age with abrupt onset associated with specific emotional event
- Dysfunction in certain settings while normal function in others
- Persistence of nocturnal erections
- Previous history of erectile dysfunction with spontaneous improvement
- Excessive life stressors—work, relationships
- Mental status findings suggestive of depression, psychosis or anxiety disorder

Organic Causes

- Vasculogenic—arterial
 - Persistent interest in sex
 - o Older age with gradual onset
 - Impaired function in all settings
 - o Presence of chronic disease (particularly diabetes, hypertension)
 - Use of prescription/over-the-counter medications associated with erectile dysfunction
 - Smoking
 - Elevated blood pressure, evidence of peripheral vascular disease (bruits, deceased pulses, skin and hair changes consistent with arterial insufficiency)
- Vasculogenic—venous
 - o Inability to maintain erection once established
 - o Prior history of priapism
 - o Local anomalies of the penis

Neurogenic Causes

- History of spinal cord/pelvic trauma or surgery
- Presence of chronic disease (diabetes, alcoholism)
- Presence of neurologic condition (multiple sclerosis, stroke)
- Abnormal neurologic examination of genitals/perineum

Hormonal Causes

- Loss of interest in sexual activity
- Small atrophic testis
- Low testosterone, elevated prolactin



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