

Erectile Dysfunction

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar members who have erectile dysfunction (ED), also known as impotence, may be eligible for coverage of treatments to assist with sexual function. ED is a type of sexual dysfunction where a man cannot get or maintain an erection adequate for sexual intercourse. It can occur due to a variety of different conditions and is commonly associated with diabetes, heart disease, Peyronie's Disease or surgery/radiation to the pelvic region. ED can be distressful for both the member and his partner. Treatment is typically performed for members with a physiological impotence, rather than psychological impotence, where an emotional process, rather than a physical process, is the primary cause. First line treatment is typically with oral medications. Failure to respond to these oral medications leads to a regimen of injectable medications, external devices, and surgical implants. The coverage criteria in this guideline are based on a combination of expert recommendations, such as those from the American Urological Association, and primary literature review.

Please refer to the drug formulary and Oscar's pharmacy benefit manager CVS/Caremark for additional information and clinical criteria for oral medications.

Definitions

"Erectile Dysfunction" (i.e., ED, Impotence) is a sexual dysfunction where a man cannot achieve or maintain an erection for sexual intercourse. Possible causes include the following:

- diseases affecting the blood supply to the penis (e.g., diabetes, heart disease, injury)
- nerve damage (e.g., spinal cord injury, diabetic neuropathy)
- Peyronie’s Disease (fibrous scar and plaque under the skin of the penis)
- psychogenic causes (e.g., an abnormal thought process)
- certain medications which can impair erectile function

“**Injectable**” medications for erectile dysfunction are typically titrated in the office under direct physician supervision and then self-administered by patients to achieve erection.

“**Vacuum Pump**” devices assist with erection by creating a vacuum to improve blood flow into the penis.

“**Penile Implants**” or penile prostheses are surgically implanted devices to assist with erection. They can be semi-rigid or inflatable depending on preference and specific member conditions.

“**Snap Gauge Testing**” refers to a device worn on the penis overnight with small plastic tabs that will break if a nocturnal erection is achieved. It is used to distinguish between psychogenic and organic causes of impotence.

“**Postage Stamp Testing**” refers to a test for nocturnal erection where a line of postage stamps are placed on the flaccid penis. Should nocturnal erection occur, the line of stamps will break at the perforated edges. It is used to distinguish between psychogenic and organic causes of impotence.

Covered Services and Clinical Indications

General Coverage Criteria

Prior to the initiation of treatment for suspected erectile dysfunction, the following diagnostic workup elements may be performed:

1. Comprehensive history and physical exam
2. Psychosocial evaluation
3. Duplex ultrasound with intracorporeal papaverine
4. Applicable only to members meeting criteria and planning to undergo for revascularization:
 - a. Dynamic infusion cavernosometry and cavernosography
 - b. Pudendal artery angiography (same revascularization)
5. All patients should have other etiologies of erectile dysfunction ruled out and/or adequately treated prior to initiation of therapy, including but not limited to:
 - a. Testosterone deficiency
 - b. Pituitary or hypothalamic dysfunction

- c. Psychogenic impotence
- 6. Lab tests that may be covered as part of the erectile dysfunction work-up:
 - a. Blood glucose
 - b. Complete blood count
 - c. Liver function tests
 - d. Creatinine
 - e. Lipid panel
 - f. PSA
 - g. Testosterone, with tests for pituitary dysfunction if abnormal
 - h. Thyroid function tests
 - i. Urinalysis
 - j. Biothesiometer, a device for measuring the threshold of perception of vibration sense, which is of use when assessing peripheral neuropathies, as seen in diabetics and groin trauma.

Medications

Oscar considers injectable (papaverine, alprostadil, or phentolamine) into the corpus cavernosum or intraurethral medications (Medical Urethral System for Erection (MUSE) for intra-urethral medication delivery) medically necessary for the treatment of erectile dysfunction when **ALL** of the following criteria are met:

1. The member has documented physiologic erectile dysfunction with other reversible causes as documented above ruled out and/or adequately treated; **and**
2. The member has tried and failed, has contraindications, or refuses to take oral medications for erectile dysfunction.

Vacuum Erectile Devices

Oscar considers vacuum erectile devices medically necessary when **ALL** of the following criteria are met:

1. The member has documented physiologic erectile dysfunction with other reversible causes as documented above ruled out and/or adequately treated; **and**
2. The prescribed erectile device meets criteria as durable medical equipment; **and**
3. The member has tried and failed conservative management, as defined by **ALL** of the following:
 - a. Sexual activity with adequate stimulation is attempted within the timeframe of drug efficacy; **and**
 - b. The member has tried injectable or intraurethral medications at least 1 time on an appropriate dose; **and**

- c. The member has had an adequate trial of oral medications, as defined by **ONE** of the following:
 - i. Tried and failed the maximum dosage of at least ONE medication, e.g., 20 mg of tadalafil (Cialis), 20 mg of vardenafil (Levitra, Staxyn), 100 mg of sildenafil (Viagra), or 200 mg of avanafil (Spedra); **or**
 - ii. Unable to tolerate a dosage less than the maximum dosage of TWO medications due to adverse effects; **or**
 - iii. Oral medications are contraindicated or refused.

Penile Prosthetic Surgery

Oscar considers penile prosthetic surgery and implant or reimplantation medically necessary when **ALL** of the following criteria are met:

- 1. The member has documented physiologic erectile dysfunction with other reversible causes as documented above ruled out and/or adequately treated; **and**
- 2. The member has tried and failed conservative management, as defined by **ALL** of the following:
 - a. Sexual activity with adequate stimulation is attempted within the timeframe of drug efficacy; **and**
 - b. The member has tried injectable or intraurethral medications at least 1 time on an appropriate dose; **and**
 - c. The member has had an adequate trial of oral medications, as defined by **ONE** of the following:
 - i. Tried and failed the maximum dosage of at least ONE medication, e.g., 20 mg of tadalafil (Cialis), 20 mg of vardenafil (Levitra, Staxyn), 100 mg of sildenafil (Viagra), or 200 mg of avanafil (Spedra); **or**
 - ii. Unable to tolerate a dosage less than the maximum dosage of TWO medications due to adverse effects; **or**
 - iii. Oral medications are contraindicated or refused.
 - d. The member has tried a vacuum erectile device for at least 1 month and applied for a maximum of 30 minutes per use.
- 3. The member meets at least **ONE** of the following:
 - a. Documented neurogenic impotence for greater than 1 year duration (i.e., diabetic neuropathy, fractured pelvis, major surgery of the pelvis or retroperitoneum, prostatectomy, or colorectal surgery, multiple sclerosis, spina bifida, spinal cord injury or disease or surgery, including syringomyelia); **or**
 - b. Documented vasculogenic impotence for greater than 1 year duration (i.e., hypertension, arterial microvascular disease, penile contusion or fracture, Peyronie's

- disease, cavernosal infection, major vascular surgery involving the aorta or femoral blood vessels, renal failure); **or**
- c. Documented impotence for greater than 1 year duration due to radiation to the pelvis or retroperitoneum.
 4. There is no evidence of drug induced impotence related to **ANY** of the following substances:
 - a. Anticholinergics
 - b. Antidepressants
 - c. Antipsychotics
 - d. CNS depressants
 - e. Anabolic steroids
 5. The member is not actively abusing alcohol or substances; **and**
 6. The member has had any depression or psychiatric illness adequately treated and/or ruled out; **and**
 7. The member has normal testosterone, prolactin, and thyroid hormone or there are specific, long-term contraindications to treating the underlying disorder.

Removal of Penile Implant

Oscar considers removal of penile implant medically necessary for any **ONE** of the following indications:

1. Infected prosthesis; **or**
2. Intractable pain directly related to prosthesis; **or**
3. Mechanical failure; **or**
4. Urinary obstruction.

Coverage Exclusions

Oscar considers the following erectile dysfunction treatments and indications experimental, investigational, unproven, and/or not medically necessary:

1. Any procedure not meeting the above criteria
2. The following genetic tests:
 - a. Angiotensin-converting enzyme (ACE) insertion/deletion polymorphism testing
 - i. Rationale for non-coverage: The existing studies have shown some potential utility of using ACE polymorphism to predict response to oral medications to treat erectile dysfunction, however these genetic tests are currently undergoing further research and have not been validated in randomized, controlled trials.¹⁴⁻¹⁶
 - b. Endothelial nitric oxide synthase polymorphism testing.¹⁶

3. Cavernous nerve mapping
 - a. Rationale for non-coverage: The existing literature is limited the small studies and those on non-human subjects. Further randomized, clinical evidence is needed to determine any potential benefit of this procedure.¹⁷
4. Corpora cavernosal electromyography
 - a. Rationale for non-coverage: CMS released a decision memo stating that this procedure would not be covered. Furthermore, a clinical trial looking into the technique was terminated due to lack of enrollment. Further randomized, clinical evidence is needed to determine any potential benefit of this procedure.¹⁸⁻¹⁹
5. Dorsal nerve conduction latency testing or evoked potential measurement
 - a. Rationale for non-coverage: The current evidence is limited to small, single institution studies with limited numbers of patients. Further randomized, clinical evidence is needed to determine any potential benefit of this procedure.²⁰
6. Penile plethysmography
 - a. Rationale for non-coverage: The current literature supports doppler ultrasound as the gold standard in assessing cavernous artery blood-flow, and notes inherent limitations of penile plethysmography. Further research is needed to identify any potential benefit of this technique. ²¹
7. Crural ligation
 - a. Rationale for non-coverage: The current evidence is limited to small, single institution studies with limited numbers of patients. Further randomized, clinical evidence is needed to determine any potential benefit of this procedure.²²⁻²³
8. Venous ligation
 - a. Rationale for non-coverage: The AUA has stated in their consensus, expert guidelines, that “there has been no new substantial evidence to support a routine surgical approach in the management of veno-occlusive ED”. Further evidence is needed to evaluate any potential benefit of this treatment.^{23-24, 35}
9. Lumbar ganglionic block or sympathectomy
 - a. Rationale for non-coverage: The current evidence is limited to small, single institution studies with limited numbers of patients. Further randomized, clinical evidence is needed to determine any potential benefit of this procedure.²⁵
10. Acupuncture
 - a. Rationale for non-coverage: Authors of one study on acupuncture for erectile dysfunction state “no definite conclusions can be drawn from this pilot study. A controlled and blinded study including more patients will be needed before any definitive conclusion can be reached”, while another concluded that “Further controlled

studies are needed to determine whether acupuncture might be a feasible and useful treatment option for erectile dysfunction in haemodialysis patients.²⁶⁻²⁷

11. Extracorporeal shock wave therapy (ESWT)

12. Percutaneous electrostimulation of the perineum

- a. Rationale for non-coverage: The current evidence is limited to small, single institution studies with limited numbers of patients. Further randomized, clinical evidence is needed to determine any potential benefit of this procedure.²⁸

13. Statin therapy

- a. Rationale for non-coverage: Statin therapy has shown some potential benefit in erectile dysfunction treatment, however further randomized, clinical trials are needed to better characterize the efficacy of this treatment. Furthermore, meta-analyses of randomized data has shown that statins increased erectile function scores by only one-third to one-half that of the current oral PDE-5 inhibitors used for ED.²⁹⁻³⁰

14. Stem cell therapy

- a. Rationale for non-coverage: Stem cell therapy for erectile dysfunction has been primarily researched in non-human models and has not yet been validated in randomized clinical trials for human use. Further research is needed to determine a potential benefit.³¹⁻³⁴

15. Penile arterial revascularization

- a. Rationale for non-coverage: The AUA expert consensus guidelines state: "The efficacy of this surgery remains unproven and controversial, largely because the selection criteria, outcome measurements, and microsurgical techniques have not been objective or standardized." "To demonstrate that penile arterial reconstructive surgery is efficacious, a large study of hundreds of patients who meet the demographic, selection, surgical, and outcome criteria of the Arterial Occlusive Disease Index Patient is needed. Such a study should focus on men who meet the criteria listed above, who have failed medical therapy, and who are followed with objective measures of sexual function."³⁵

16. Nocturnal penile testing or rigidity testing, including rigiscan device

- a. Rationale for non-coverage: AUA expert consensus guidelines do not mention nocturnal penile or rigidity testing in the workup or treatment of erectile dysfunction. Furthermore, the techniques used to test for nocturnal erections (e.g. stamp test, snap gauge test) have historically been highly operator dependent and difficult to reproduce.³⁵

Applicable Billing Codes (HCPCS/CPT Codes)

Erectile dysfunction treatment	
CPT/HCPCS Codes covered if criteria are met:	
<i>Code</i>	<i>Description</i>
37788	Penile revascularization, artery, with or without vein graft
54110 - 54112	Excision of penile plaque (Peyronie disease)
54200 - 54205	Injection procedure for Peyronie disease
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)
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 pump, cylinders, and reservoir
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
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
74445	Corpora cavernosography, radiological supervision and interpretation
78012	Thyroid uptake, single or multiple quantitative measurement(s) (including stimulation, suppression, or discharge, when performed)
80061	Lipid panel
80076	Hepatic function panel
81000 - 81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents
82565	Creatinine; blood
82947	Glucose; quantitative, blood (except reagent strip)
84146	Prolactin
84152 - 84154	Prostate specific antigen (PSA)
84402 - 84403	Testosterone; free or total
84410	Testosterone; bioavailable, direct measurement (eg, differential precipitation)
84443	Thyroid stimulating hormone (TSH)
84479	Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)
85025 - 85027	Blood count; complete (CBC), automated
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

	limited study
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
J0270	Injection, alprostadil, 1.25 mcg
J0275	Alprostadil urethral suppository
J2440	Injection, papaverine HCl, up to 60 mg
J2760	Injection, phentolamine mesylate, up to 5 mg
L7900	Male vacuum erection system
L7902	Tension ring, for vacuum erection device, any type, replacement only, each
ICD-10 codes covered if criteria are met:	
<i>Code</i>	<i>Description</i>
N52.01 - N52.1; N52.2 - N52.39	Male erectile dysfunction [physiological impotence]
ICD-10 codes not covered:	
<i>Code</i>	<i>Description</i>
F52.0	Hypoactive sexual desire disorder
F52.1, F52.8	Psychosexual dysfunction and other specified psychosexual dysfunctions
F52.21	Male erectile disorder [psychogenic impotence]
F52.32	Male orgasmic disorder
F52.4	Premature ejaculation
F53.3	Abuse of steroids or hormones
N52.2	Drug-induced erectile dysfunction
N52.8 - N52.9	Other and unspecified male erectile dysfunction

R37	Sexual dysfunction, unspecified
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CPT/HCPCS codes not covered for indications listed in this guideline:	
<i>Code</i>	<i>Description</i>
0019T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation
38242	Allogeneic lymphocyte infusions
51792	Stimulus evoked response (e.g., measurement of bulbocavernosus reflex latency time)
64565	Percutaneous implantation of neurostimulator electrodes; neuromuscular
64580	Incision for implantation of neurostimulator electrodes; neuromuscular
64585	Revision or removal of peripheral neurostimulator electrodes
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
81479	Unlisted molecular pathology procedure [when used for Endothelial nitric oxide synthase polymorphism testing]
82164	Angiotensin I - converting enzyme (ACE)
83550	Iron binding capacity

84066	Phosphatase, acid; prostatic
95907 - 95913	Nerve conduction studies
95925 - 95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; iontophoresis, each 15 minutes
97810 - 97814	Acupuncture
ICD-10 codes not covered for the above billing codes:	
<i>Code</i>	<i>Description</i>
N52.01 - N52.9	Male erectile dysfunction

CPT/HCPCS codes never covered:	
<i>Code</i>	<i>Description</i>
37790	Penile venous occlusive procedure
54240	Penile plethysmography
54250	Nocturnal penile tumescence and/or rigidity test

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