Oscar Clinical Guideline: Erectile Dysfunction (CG037, Ver. 12)

Erectile Dysfunction

Summary

The Plan members who have erectile dysfunction (ED), also known as impotence, may be eligible for 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 their partner. Treatment is typically performed for members when physiological impotence, which is a physical process, rather than psychological impotence, which is an emotional 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/or surgical implants. The medical necessity 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, pharmacy clinical guideline, and pharmacy benefit manager 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, but not limited to the following:

- Vascular diseases affecting the blood supply to the penis (e.g., diabetes, heart disease, injury)

- Neuropathic such as nerve damage (e.g., spinal cord injury, diabetic neuropathy, pelvic radiation)
- Psychosocial (e.g. alcohol and/or drug use, certain behavioral health disorders, or fear of sex)
- Hormonal (e.g. testosterone deficiency, pituitary dysfunction, and thyroid disorders) as well as certain medications including anticholinergics, antipsychotics, seizure medication, and antidepressants that can impair erectile function
- Miscellaneous (e.g., Peyronie's Disease with fibrous scar and plaque under the skin of the penis)

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

"Oral" medications are taken by mouth.

"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.

"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.

"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.

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

Clinical Indications

General Criteria

Prior to the initiation of treatment for suspected erectile dysfunction, the following diagnostic tests and assessments may be medically necessary to formulate a treatment plan:

1. Comprehensive history (e.g., sexual and medical 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 medically necessary as part of the erectile dysfunction work-up:
    a. Complete Blood Count
    b. Comprehensive Metabolic Panel
    c. Follicle Stimulating Hormone
    d. Hemoglobin A1c
    e. Liver function tests
    f. Lipid panel
    g. Luteinizing Hormone
    h. Prostate Specific Antigen
    i. Serum testosterone, with tests for pituitary dysfunction if abnormal
    j. Thyroid panel
    k. Urinalysis

Medications

The Plan considers injectable medications (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; *and*
3. An in-office test should be performed to demonstrate efficacy.

Vacuum Erectile Devices

The Plan 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 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

The Plan 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. 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; *and*
    b. Sexual activity with adequate stimulation is attempted within the timeframe of drug efficacy; *and*
    c. The member has tried and failed a vacuum erectile device for at least 1 month and applied for a maximum of 30 minutes per use; *and*
    d. The member has tried and failed injectable or intraurethral medications at least 1 time on an appropriate dose, unless contraindicated.
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, 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 no current urinary tract, cutaneous, or systemic infection at the time of surgery; *and*
8. If the member has comorbidities such as diabetes, documentation must show proper management. Any risks that would cause potential complications or intolerance to healing post surgery should be evaluated prior to surgery; *and*
9. The member has been assessed for normal hormone levels (e.g., testosterone, prolactin, and thyroid hormone) or there are specific, long-term contraindications to treating the underlying hormone disorder.

Removal of Penile Implant

The Plan 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.

Experimental or Investigational / Not Medically Necessary

The Plan 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: 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.
    b. Endothelial nitric oxide synthase polymorphism testing.
3. Cavernous nerve mapping
    a. Rationale: 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.
4. Corpora cavernosal electromyography
    a. Rationale: 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.
5. Dorsal nerve conduction latency testing or evoked potential measurement

    a. Rationale: 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
6. Extracorporeal shock wave therapy (ESWT):
    a. Rationale: Extracorporeal shock wave therapy (ESWT) is considered investigational as per 2018 AUA Guideline statement 23: For men with ED, low-intensity extracorporeal shock wave therapy (ESWT) should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C). Based on review of trials, the treatment's ability to restore normal erectile function is unproven, the duration of treatment effects is not well-established, and increased financial burden associated with obtaining the treatment when comparing the availability of other treatments that are less burdensome and known to be effective.
7. Penile plethysmography
    a. Rationale: 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.
8. Crural ligation
    a. Rationale: 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.
9. Venous ligation
    a. Rationale: 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.
10. Lumbar ganglionic block or sympathectomy
    a. Rationale: 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.
11. Acupuncture
    a. Rationale: 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 patients."
12. Percutaneous electrostimulation of the perineum
    a. Rationale: 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.

13. Statin therapy
    a. Rationale: 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 have 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.
14. Stem cell therapy
    a. Rationale: 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. Additionally, the 2018 AUA guidelines list ESWT as an investigational treatment.
15. Penile arterial revascularization
    a. Rationale: 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."
16. Nocturnal penile tumescence or rigidity testing, including rigiscan device
    a. Rationale: AUA expert consensus guidelines state nocturnal penile or rigidity testing is prone to false negatives 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.
17. Biothesiometry
    a. Rationale: A biothesiometer is a test that uses electromagnetic vibrations to measure sensitivity and neuropathies, as seen in diabetics and groin trauma. The AUA and other sources conclude that data is limited on the clinical utility of this device.
18. Uncontrolled Diabetes
    a. Rationale: As per 2018 AUA guidelines, erectile dysfunction (ED) is one of the most common complications of diabetes mellitus and approximately 20% of men with ED also had diabetes. Diabetes as well as other risk factors such as age, smoking, cardiovascular disease show an increased correlation to ED. In some cases, the underlying cause of ED may be related to undiagnosed diabetes and therefore, proper screening and management of diabetes should be performed.
    Furthermore, patients with diabetes show increased infection risk related to penile prosthetic surgery compared to patients without diabetes as reflected in multiple studies (Adamsky et al., 2018; Gross et al., 2019; Lipsky et al., 2019). As per 2022 consensus report by ADA and EASD, there should be a holistic approach for diabetes management that considers medical management, lifestyle management, individualized target goals

for blood glucose and HbA1c. Therefore, when a member has uncontrolled diabetes and without any diabetes management or adherence to goals, the request for penile prosthetic surgery should be considered not medically necessary.

Applicable Billing Codes (HCPCS/CPT Codes)

Table 1	
Erectile dysfunction treatment	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
37788	Penile revascularization, artery, with or without vein graft
54110	Excision of penile plaque (Peyronie disease)
54111	Excision of penile plaque (Peyronie disease); with graft to 5 cm in length
54112	Excision of penile plaque (Peyronie disease); with graft greater than 5 cm in length
54200	Injection procedure for Peyronie disease
54205	Injection procedure for Peyronie disease; with surgical exposure of plaque
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	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy

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; automated, without microscopy
82565	Creatinine; blood
82947	Glucose; quantitative, blood (except reagent strip)
84146	Prolactin
84152	Prostate specific antigen (PSA); complexed (direct measurement)
84153	Prostate specific antigen (PSA); total
84154	Prostate specific antigen (PSA); free
84402	Testosterone; free
84403	Testosterone; 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	Blood count; complete (CBC), automated
85027	Blood count; complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)
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 considered medically necessary if criteria are met for the above CPT/HCPCS codes:	
Code	*Description*
N52.01 - N52.03	Vasculogenic erectile dysfunction
N52.1	Erectile dysfunction due to diseases classified elsewhere
N52.31 - N52.39	Postprocedural erectile dysfunction
ICD-10 codes *not* considered medically necessary for the above CPT/HCPCS codes:	
Code	*Description*
F52.0	Hypoactive sexual desire disorder
F52.1	Sexual aversion disorder
F52.21	Male erectile disorder
F52.32	Male orgasmic disorder
F52.4	Premature ejaculation
F52.8	Other sexual dysfunction not due to a substance or known physiological condition
F53.3	Abuse of steroids or hormones
N52.2	Drug-induced erectile dysfunction
N52.8	Other male erectile dysfunction
N52.9	Male erectile dysfunction, unspecified
R37	Sexual dysfunction, unspecified

Table 2	
CPT/HCPCS codes considered experimental or investigational for indications listed in this guideline (please refer to the ICD-10 codes below):	
Code	*Description*
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)
54250	Nocturnal penile tumescence and/or rigidity test
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 • Due to multiple tests represented by this CPT/HCPCS code, specific exclusions are indicated: • When this code is billed for endothelial nitric oxide synthase polymorphism testing for erectile dysfunction, it is considered experimental or investigational
82164	Angiotensin I - converting enzyme (ACE)
83550	Iron binding capacity

84066	Phosphatase, acid; prostatic
95907	Nerve conduction studies; 1-2 studies
95908	Nerve conduction studies; 3-4 studies
95909	Nerve conduction studies; 5-6 studies
95910	Nerve conduction studies; 7-8 studies
95911	Nerve conduction studies; 9-10 studies
95912	Nerve conduction studies; 11-12 studies
95913	Nerve conduction studies; 13 or more studies
95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
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	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient

97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
ICD-10 codes considered experimental or investigational for the above billing codes in this table 2:	
Code	*Description*
N52.01 - N52.9	Male erectile dysfunction

Table 3	
CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
37790	Penile venous occlusive procedure
54240	Penile plethysmography

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