Guidelines for Medical Necessity Determination for the Treatment of Erectile Dysfunction

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for the treatment of erectile dysfunction (ED). These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 415.000: *Acute Inpatient Hospital Services*; 130 CMR 433.000: *Physician Services*; 130 CMR 410.000: *Outpatient Hospital Services*; 130 CMR 450.000: *Administrative and Billing Regulations*; Subchapter 6 of the *Physician Manual*; and Subchapter 6 of the *Acute Outpatient Hospital Manual* for information about coverage, limitations, service conditions, and other prior-authorization requirements (PA) applicable to this service.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care Organization, Senior Care Organization (SCO), or a Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for treatment of erectile dysfunction. MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

SECTION I. GENERAL INFORMATION

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The American Urological Association (AUA) 2018 erectile dysfunction (ED) guideline defines ED as "…the consistent or recurrent inability to attain and/or maintain penile erection sufficient for sexual satisfaction, including satisfactory sexual performance." According to the AUA guideline, independent risk factors for ED are similar to those for cardiovascular disease. These include, among others, smoking, diabetes mellitus, hypertension, dyslipidemia and obesity. Between 20% and 85% of men with diabetes, and approximately 35% of men with dyslipidemia, experience ED (AUA, 2018). Moreover, approximately 75% of men with heart failure experience ED, and causes of ED in men with heart failure include arterial insufficiency, endothelial dysfunction, reduced cardiac capacity, and side effects of medication for cardiovascular disease (Rastogi, 2005). In addition, surgery (especially radical prostate and bladder surgery for cancer) and radiotherapy can injure nerves and arteries near the penis, causing ED (Chung, 2014). Injury to the penis, spinal cord, prostate, bladder, and pelvis can lead to ED by harming nerves, smooth muscles, arteries, and fibrous tissues of the corpora cavernosa.

Penile prosthesis implantation is a treatment option for men with ED who have failed less invasive treatments. For those without other comorbidities, oral phosphodiesterase-5 (PDE5) inhibitors such as sildenafil and tadalafil are usually first-line therapies, unless contraindicated. Recent meta-analyses have found that all available oral PDE5 inhibitors are effective, compared with placebo, with similar efficacy of the various PDE5 inhibitors (Allen, 2019). For men with testosterone deficiency, PDE5 inhibitors can be supplemented with testosterone therapy (AUA, 2018). If oral medications are not sufficient, injectable medications or vacuum devices, which are a noninvasive modality, are often

recommended before a penile prosthesis. Underlying causes for erectile dysfunction are important to identify and address, if possible, with appropriate interventions.

The U.S. Food and Drug Administration (FDA) considers the rigid penile implant as a Class II device. The semi-rigid rods are implanted into the corpora cavernosa of the penis to provide rigidity. Inflatable penile implants are considered Class III devices by the FDA. Inflatable cylinders are implanted in the penis and are connected to a reservoir filled with fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. Penile rigidity is achieved when the cylinders are filled with fluid.

Penile prothesis implantation may be used for the acute management of an acute ischemic priapism that lasts over 36 hours—the rationale being ease of placement and less penile shortening, which occurs due to corpus cavernosum fibrosis (Yücel, 2018). Peyronie's disease with erectile dysfunction unresponsive to medical therapy is also an accepted indication for penile prosthetic placement (Sokolakis, 2021).

2 SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for ED on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure, including postoperative recovery.

1. **EXTERNAL DEVICES**

   MassHealth considers the external penile vacuum pump device medically necessary durable medical equipment (DME) when it is prescribed by a physician as an alternative or in combination with other therapies for ED.

2. **IMPLANTABLE DEVICES**

   MassHealth considers implantation of semi-rigid penile prostheses or inflatable penile prostheses (implantable penile pumps) medically necessary for members with documented physiologic ED when all of the following criteria are met:

   - Absence of active alcohol or substance abuse;
   - Absence of drug-induced impotence related to anabolic steroids, anticholinergics, antidepressants, antipsychotics, or central nervous system depressants;
   - Absence of *untreated* depression or psychiatric illness;
   - Proved ineffectiveness or contraindication of non-surgical methods;
   - Normal prolactin and thyroid hormone levels;
   - Normal serum testosterone levels and
   - History of organic disease, including any one or more of the following:
     - Documented injury to perineum/genitalia;
     - Major pelvic trauma affecting bladder and/or anal and/or erection control;

- Major vascular surgery involving aorta or femoral blood vessels;
- Retroperitoneal surgery;
- Neurological disease (e.g., diabetic neuropathy, spinal cord injury);
- Peyronie's disease;
- Renal failure;
- Spinal cord injury;
- Prostate, bladder, bowel or spinal surgery;
- Vascular insufficiency or venous incompetence documented by dynamic infusion cavernosometry and cavernosography (DICC);
- Venous leak of the penis; or
- Other medical conditions not otherwise listed here that result in similar dysfunction, whose criteria will be at the discretion of MassHealth review.

Removal of a penile implant is considered medically necessary for infected prosthesis, intractable pain, mechanical failure, or urinary obstruction.

Reimplantation of a penile implant is considered medically necessary for persons who meet medical necessity criteria above for a penile implant and whose prior prosthesis was removed for medically necessary indications.

3. **SURGICAL RE-VASCULARIZATION**

MassHealth considers penile re-vascularization for vasculogenic ED medically necessary only in men under 55 years old who meet all of the following criteria:

- A focal blockage of arterial inflow is demonstrated by duplex Doppler ultrasonography or arteriography;
- Normal corporeal venous function;
- Member is not actively smoking;
- Member is not diabetic and has no evidence of systemic vascular occlusive disease; and
- The erectile dysfunction is the direct result of an arterial injury caused by blunt trauma to the pelvis and/or perineum.

B. NON-COVERAGE

MassHealth considers the following treatments experimental and investigational for erectile dysfunction because their effectiveness has not been established, and generally does not consider the following treatments medically necessary.

- Exogenous testosterone replacement therapy and topical creams or gels containing vasodilators
- External penile pumps for indications other than the one listed above, including for the prevention of ED following prostatectomy
- Implantable penile prostheses for indications other than the one listed above
- Penile re-vascularization for indications other than the one listed

- Acupuncture
- Acoustical wave therapy (Alpha Wave SwissWave Protocol)
- Botulinum toxin
- Endovascular treatment (e.g., angioplasty and drug-eluting stent placement for the treatment of vasculogenic ED)
- Epalrestat
- Extracorporeal shock wave therapy (ESWT)
- Gene therapy
- Pelvic floor muscle training (for ED following radical prostatectomy)
- Percutaneous electrostimulation of the perineum.
- Stem cell therapy (including adipose-derived stem cells and mesenchymal stem cells)
- Tacrolimus

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SECTION III: SUBMITTING CLINICAL DOCUMENTATION

A. **REQUESTS FOR TREATMENT FOR ED** must be submitted by the MassHealth-enrolled qualified health professional performing the treatment and accompanied by clinical documentation that supports the medical necessity for the procedure. The following workup and tests are medically necessary for the diagnosis of ED.

B. **REQUIRED DIAGNOSTIC WORKUP:**

1. Comprehensive history and physical examination (including medical and sexual history and psychosocial evaluation)
2. Laboratory tests (must be done within the preceding 12 months):
    a. Blood glucose and/or HbA1c within diabetes control range
    b. Complete blood count
    c. Creatinine
    d. Hepatic panel
    e. Lipid profile
    f. Prostate specific antigen
    g. Serum testosterone collected before 10:00 a.m.
        i. If testosterone level is abnormally low, repeat testosterone test to confirm low testosterone level
        ii. If repeat testosterone level is below normal: consider FSH, LH, and prolactin
        iii. Endocrine consultation if FSH or LH or prolactin abnormal
        iv. If low testosterone with normal FSH, LH, and prolactin, consider testosterone supplementation therapy with PDE5 inhibitor therapy prior to prosthetic

h. The above tests are *not required* for:

i. Acute ischemic priapism lasting greater than 36 hours

ii. Prior history of ischemic priapism greater than 24 hours with failed medical therapy

iii. Peyronie's disease with erectile dysfunction refractory to erectile dysfunction medical therapy (oral and/or injectables)

3. Progress notes documenting that any co-existing medical issues are being appropriately managed and are reasonably controlled

4. Psychological assessment prior to offering implantable device if concern exists regarding patient acceptance of device

5. Progress notes confirming erectile dysfunction refractory to medical therapies or that medical therapies are contraindicated

6. In the case that injectable medications, oral and transdermal medications, and external devices are deemed ineffective, a complete assessment for requiring alternative treatment (including implantable devices or surgical revascularization) should be submitted.

C. **A LETTER FROM THE SURGEON** performing a surgical procedure for ED, if applicable, must attest to all the following:

1. The member meets the clinical criteria for coverage described in Section II.A. of these Guidelines; and

2. The surgeon has discussed risks and complications of the proposed surgery, including the surgeon's own complication rates, and has obtained informed consent from the member.

D. As noted above, **ALL CLINICAL INFORMATION** must be submitted by the MassHealth-enrolled qualified health care professional administering treatment or performing the surgery, in the case of penile implant.

E. The decision between **INFLATABLE PROTHESIS AND RIGID PROSTHESIS** is to be at the discretion of the treating professional.

F. **OPTIONAL DIAGNOSTIC WORKUPS** (may be submitted as part of clinical documentation but are not required for coverage):

1. Biothesiometry

2. Nocturnal Penile Tumescence Testing to exclude psychogenic causes if indicated

3. Pharmacological response test for erectile dysfunction (using vasoactive drugs, e.g., papaverine HCl, phentolamine mesylate, prostaglandin E1)

4. For members who are to undergo penile re-vascularization and meet the medical necessity criteria for penile re-vascularization:

a. Dynamic infusion cavernosometry and cavernosography

b. Duplexscan (Doppler and ultrasound) in conjunction with intracorporeal papaverine in patients who may benefit from revascularization procedures

c. Pudendal arteriography (angiography)

G. **CLINICAL INFORMATION** must be submitted by the MassHealth-enrolled qualified health professional performing the procedure. Providers are strongly encouraged to submit requests electronically. Providers must submit the request for PA and all supporting documentation using the Provider Online Service Center (POSC), or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at www.mass.gov/masshealth) and attaching all supporting documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900.

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These Guidelines are based on review of the medical literature and current practice in the treatment of erectile dysfunction. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

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