Erectile dysfunction treatments other than pharmaceuticals

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Policy contains: surgical revascularization; penile vacuum pump; erectile dysfunction; penile prosthesis; impotence.

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Coverage policy

Vacuum erection devices, penile prosthesis implantation, and penile arterial reconstruction for erectile dysfunction are clinically proven and, therefore, medically necessary when the following criteria are met:

- The member is diagnosed with erectile dysfunction.
- Conservative treatments have been attempted for at least 12 months and have failed (Burnett, 2018).

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

Re-implantation of a penile implant is considered medically necessary for members whose prior prosthesis was removed for medically necessary indications.

Limitations

All other nonmedicinal interventions for erectile dysfunction are investigational/not clinically proven, and therefore, not medically necessary — including venous surgery, low-intensity extracorporeal shock wave

therapy, intra-cavernosal stem cell therapy, and platelet-rich plasma therapy (Burnett, 2018).

Alternative covered services

Various medications (not addressed in this policy).

Background

Erectile dysfunction, also referred to as impotence, is defined as the inability to achieve or maintain an erection that is sufficient for satisfactory sexual performance. Some form of erectile dysfunction will affect 40% of men in their 40s; 50% of men in their 50s; 60% of men in their 60s; and higher rates for men over 70 (Ferrini, 2017).

Erectile dysfunction was once believed to be a psychological disease, but more than 80% of cases are now considered to have an organic etiology. Conditions associated with the disorder include hypogonadism, lower urinary tract symptoms, benign prostatic hypertrophy, hypertension, cardiovascular disorder, smoking, excess alcohol intake, obesity, dyslipidemia, diabetes mellitus, metabolic syndrome, stress, anxiety, and depression. Reactions to various surgeries and medications can also cause erectile dysfunction (Yafi, 2016).

Diagnosing erectile dysfunction includes a work-up of patients seeking medical care for the disorder. The diagnosis can only be made with establishment of an accurate medical and sexual history; a careful general and focused genitourinary examination; and a minimum number of hormonal and routine biochemical tests. Provider questioning to the patient must be done in a manner to minimize patient embarrassment (Yafi, 2016).

Erectile dysfunction is a highly under-treated condition. A study of 6.2 million males diagnosed with erectile dysfunction found that only 25.4% were treated (at least one filled prescription for phosphodiesterase type 5 inhibitor, injection or urethral prostaglandins, or androgen replacement) over a 12-month period. Men older than age 60 were significantly less likely ($P < .0001$) to be treated than males ages 40 – 59 (Frederick, 2014).

Recommended treatment of men with erectile dysfunction should always include encouragement of patient lifestyle changes that address known causes of the disorder. These changes include diet, increased physical activity, and cessation of alcohol consumption or tobacco use. The most conservative first-line treatment for the disorder is prescribed oral phosphodiesterase type 5 inhibitors; testosterone therapy can be added if the patient also has hypogonadism (Burnett, 2018).

When conservative treatments do not result in improvements, erectile dysfunction can be treated using several invasive approaches, namely:

- Penile Prosthesis. Inflatable pumps or semi-rigid/malleable rods are types of prostheses implanted into the penis and scrotum in a one- to two-hour procedure. Infections can occur, along with complications such as glans bowing, reservoir complications, corporal crossover, and perforations (Sadeghi-Nejad, 2013). The procedure has traditionally been performed in an inpatient setting, but an increasing proportion is performed in ambulatory surgery centers (Segal, 2020).

- Vacuum Erection Device. An acrylic cylinder with a pump may be attached directly to the end of the penis, and a constriction ring or band is placed on the cylinder at the other end, which is applied to the

body. The cylinder and pump create a vacuum to help the penis become erect, while the band or constriction ring helps maintain the erection (Hoyland, 2013).

- Penile Arterial Reconstruction. Vascular surgery can reconstruct arteries to improve blood flow to the penis. Recent types of this surgery include circumferential incision plus a median pubic longitudinal approach with acupuncture-assisted local anesthesia and penile venous stripping surgery (Molodysky, 2013).

Dietary supplements and other natural treatments are also used to treat erectile dysfunction; efficacy reviews in the professional literature are limited.

Findings

The American Urological Association guideline on erectile dysfunction recommended six types of treatments that may be considered. Three are medications, while the others are vacuum erection devices, penile prosthesis implantation, and penile arterial reconstruction — for each, the guideline states that patients must be informed of potential risks and benefits before treatment starts. Treatments not recommended are venous surgery, low-intensity extracorporeal shock wave therapy, intracavernosal stem cell therapy, and platelet-rich plasma therapy (Burnett, 2018).

The Canadian Urological Association agreed that oral medications should be first-line therapy. However, second-line therapies and surgery are also important options in treating confirmed cases of erectile dysfunction (Bella, 2015). The European Association of Urology also supported these first- , second- , and third-line therapies (Hatzimouratidis, 2016). The British Society for Sexual Medicine guideline supported use of vacuum erection devices and penile prosthesis implantation, but did not mention penile arterial reconstruction (Hackett, 2018).

The American Academy of Family Physicians guideline recommended lifestyle changes (including tobacco cessation, exercise, weight loss, control of diabetes, hypertension, and hyperlipidemia), plus oral phosphodiesterase-5 inhibitors as first-line treatments for erectile dysfunction. The Academy recommended alprostadil and vacuum devices for second-line therapy, and surgically implanted penile prostheses when other treatments have failed (Rew, 2016).

The American Society of Clinical Oncology endorsed a guideline, including a recommendation that people with cancer be counseled about sexual health and dysfunction related to cancer. The guideline states that if medical management does not succeed, medication such as phosphodiesterase type 5 inhibitors may be beneficial, and surgery remains an option for males with erectile dysfunction (Carter, 2018).

A number of systematic reviews or meta-analyses and other large-scale studies have appeared in the professional literature addressing safety and effectiveness of various treatments for erectile dysfunction.

Penile Prosthesis

- A review of 50 studies found 30% of males with penile prosthesis discontinued having sex, mostly due to device complications, lack of a partner or loss of sexual interest. Men who reported side effects to a healthcare professional were significantly less likely to discontinue treatment (Williams, 2021).
- A systematic review of 14 studies (n = 334) compared patients who underwent penile prosthesis, randomized by whether or not the procedure followed a solid organ transplant (which elevates risk of erectile dysfunction). The group with solid organ transplants did not show increased complications, but were more likely to experience future surgical complications (Dick, 2020).

- A review of 91 articles demonstrated that prosthetic infection rates up to 24.6% occur, but most facilities report rates below 5%, which authors attribute to increased use of antimicrobial coating (Mahon, 2020).
- A literature review of 40 studies (n = 175,592) concluded infection-retardant-coated penile prosthesis and primary (first) surgery of prosthesis placement lower infection risk (Carvajal, 2020).
- A systematic review of 14 studies (n = 9,910 patients with a first-time penile implant) determined that the infection rate for patients whose prosthesis did not have an infection retardant coating was significantly greater than those who had such a coating (2.32% versus 0.89%, or $P < .01$) (Mandava, 2012).
- A retrospective study of 883 patients with erectile dysfunction who underwent malleable, two-piece, or three-piece penile prosthesis implants and were followed for an average of 49 months, showed couples' satisfaction was significantly highest in the two- and three-piece group. The highest rate of revision surgery due to penile corporal perforation was in the malleable group ($P = .021$), whereas the highest rate of revision surgery due to penile implant malfunction occurred in the three-piece implant group ($P = .001$) (Cayan, 2019).
- In a review of only studies with at least a five-year follow up, five- and 10-year device survival of prosthesis implant was 90.4% and 86.6%, respectively. Eight- and 10-year infection rates were 1.5% and 1.8%. Authors maintain that prosthesis implant is the gold standard for erectile dysfunction among patients refractory to medicinal treatment (Dick, 2019).

Vacuum Erection Device

- A systematic review/network meta-analysis of 24 randomized trials (n = 3,500) of males with erectile dysfunction after prostatectomy found vacuum constriction devices were the most effective intervention in improving erectile function scores three months of surgery. Devices improved outcomes when added to drugs, with no change after medication was added to vacuum device monotherapy (Feng, 2021).
- A systematic review/meta-analysis of 39 randomized trials of erectile dysfunction after prostatectomy revealed erection function scores were significantly higher when vacuum constriction devices were used, compared to controls, six to nine months after surgery ($P = .003$) (Feng, 2020).
- A systematic review of 11 studies of patients with erectile dysfunction following robot-assisted prostatectomy concluded that of all treatments combined with phosphodiesterase-5 inhibitors, vacuum pump erectile devices had the "most promising association" (Marchioni, 2020).
- A systematic review or meta-analysis of six controlled trials (n = 273) assessed vacuum therapy for penile rehab after radical prostatectomy. Early use of vacuum therapy significantly improved erectile function and penile shrinkage. Few adverse events and no serious side effects were reported (Qin, 2018).
- A study of 1,500 men with organic erectile dysfunction participated in vacuum constrictive device training. At the first session, 87.4% attained a full erection, while the others did so after one week. The ability to perform vaginal penetration was 94.6%. Erectile scores of improved from 9.3 to 27.5 ($P < .05$) (Khayyamfar, 2014).

Penile Arterial Reconstruction

- A review of 25 nonrandomized studies of penile revascularization surgery found the subjective cure rate in men under 30 was better than in older men ($P = .001$). Venous leak and history of smoking influenced success rates (Babaei, 2009).

- A systematic review and meta-analysis of 16 articles (n = 374) assessed efficacy and safety of endovascular therapy in patients with veno-occlusive dysfunction or arterial insufficiency. Overall clinical success rates for the groups were 59.8% and 63.2%; complications occurred in 5.2% and 4.9% (Doppalapudi, 2019).
- A study of 96 patients with (veno-occlusive) erectile dysfunction found pelvic venoablation, without any drugs, allowed 80.21% to have erections sufficient for vaginal insertion within three months (Herwig, 2015).
- A study of 110 patients tracked an average of 73.2 months after penile revascularization surgery showed an increase in erection function from 7.3 to 16.8 points. The three-month success rate (> 5-point increase), was 81.8% at three months, and 63.6% at five years (Kayigil, 2012).

Extracorporeal shock wave therapy

- A meta-analysis of seven controlled trials (n = 522) compared low-intensity extracorporeal shock wave therapy for erectile dysfunction with sham therapy. Significant improvements for the treatment group were observed for erectile function ($P < .00001$), while the best improvements were for moderate or severe erectile dysfunction. Follow up in five of seven studies were five weeks or less; in the other two, which followed subjects for 12 months, only one showed greater efficacy after treatment (Dong, 2019).
- A systematic review of low-intensity shock wave therapy for erectile dysfunction included 11 studies (n = 799). Nine studies found a significant improvement in erectile function after six months. However, after 12 months, two of five studies found a plateauing, and the other three a deterioration (Brunckhourst, 2019).
- A meta-analysis of 10 controlled trials (n = 873) found low-intensity extracorporeal shock wave therapy for erectile dysfunction improved function ($P = .0009$) and patient outcomes ($P < .00001$) (Sokolakis, 2019).
- A meta-analysis of eight randomized controlled trials (n = 595) of low-intensity extracorporeal shock wave therapy showed that, compared with controls, improvements were observed in the International Index of Erection Function ($P = .008$) and erection hardness score ($P < .01$). Scores were markedly increased at 4 and 24 weeks after treatment. No significant adverse events were reported (Mo, 2019).
- A systematic review or meta-analysis documented that, based on nine studies (n = 637), low-energy extracorporeal shock wave therapy significantly improved erection function ($P = .003$) for three months (Man, 2018).
- A systematic review or meta-analysis of 15 studies (n = 277) found low-intensity extracorporeal shock wave treatment was 8.31 times more effective than sham treatment, and improved erectile function by 2.5 times more, one month after treatment (Zou, 2017).
- A systematic review or meta-analysis of 14 trials (n = 833) showed low-intensity extracorporeal shock wave therapy improved erectile function ($P < .0001$) and erection hardness score ($P < .01$), and that efficacy could last at least three months (Lu, 2017).

Other treatments

- A review of 19 articles addressing relatively new interventions for erectile dysfunction documented evidence supporting the use of two microsurgical treatments, namely microvascular arterial bypass penile revascularization surgery and cavernous nerve graft reconstruction (Shauly, 2019).
- A review of the literature on erectile function following radical prostatectomy could not agree on one type of treatment that was superior to others (Mulhall, 2013).

References

On September 2, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “erectile dysfunction,” “extracorporeal shock wave therapy,” “penile arterial reconstruction,” “penile prosthesis implantation,” and “vacuum erection devices.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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