Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	**Submission Date**: 1/2/2025
Policy Number: ccp.1433	**Effective Date:** 1/2020 **Revision Date:** December 1, 2024
Policy Name: Erectile dysfunction treatments other than pharmaceuticals	

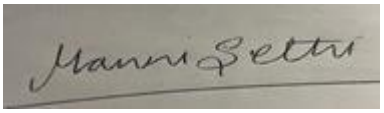
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Community HealthChoices

Erectile dysfunction treatments other than pharmaceuticals

Clinical Policy ID: CCP.1433

Recent review date: 12/2024

Next review date: 4/2026

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

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Vacuum erection devices and penile arterial reconstruction are clinically proven and, therefore, may be medically necessary when the following criteria are met (Burnett, 2018):

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

Note: This policy does not address penile prosthesis implants.

Limitations

Other non-pharmaceutical 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).

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 to 59 years (Frederick, 2014).

Conservative treatment options consist of lifestyle changes, psychosexual therapy, oral phosphodiesterase type 5 inhibitors, and prostaglandin E1 intracavernous injections. When conservative treatments cannot be tolerated or do not result in improvements, erectile dysfunction can be treated using non-invasive and invasive approaches. A vacuum erection device is an acrylic cylinder with a pump 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 (Shindel, 2022).

Surgical options include penile arterial reconstruction and penile prosthesis placement, which has replaced venous surgery as the recommended standard of care. Penile arterial reconstruction can improve blood flow to the penis. It is generally reserved for select patients, such as healthy young men with either congenital or traumatic erectile dysfunction, not with arteriosclerosis as a cause (Shindel, 2022).

Findings

Guidelines

The American Urological Association guideline on erectile dysfunction recommended six types of treatments. Three are medications, while the others include vacuum erection devices and penile arterial reconstruction — for both, the guideline states that patients must be informed of potential risks and benefits before treatment starts. Penile arterial reconstruction may be considered for young men with erectile dysfunction and focal pelvic/penile arterial occlusion and without documented generalized vascular disease or veno-occlusive dysfunction. A vacuum erection device may be an option. 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 British Society for Sexual Medicine guideline supported use of vacuum erection devices 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).

Evidence reviews

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.

Vacuum erection devices

- A systematic scoping review of 16 studies, including seven randomized controlled trials, documented improvements after vacuum erection, both with and without phosphodiesterase type 5 inhibitors, in International Index of Erectile Function scores, conservation of penile length, and satisfactory intercourse (Pirola, 2024).
- A systematic review/network meta-analysis of 24 randomized trials (n = 3,500) of males with erectile dysfunction after prostatectomy found vacuum constriction devices (four trials) were the most effective intervention in improving erectile function scores three months of surgery. Devices improved outcomes when added to drugs, but there was no improvement when medication was added to vacuum device monotherapy (Feng, 2021).

Penile arterial reconstruction

- 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 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 (low-intensity)

- A systematic review/meta-analysis of 16 randomized controlled trials (n = 1,054) found treatment of erectile dysfunction with shock wave therapy versus placebo (sham treatment or no treatment) improved scores of International Index of Erectile Function ($P < .00001$) and Erectile Hardness Scale ($P = .002$). The impact of age and comorbidities (e.g., hypertension, diabetes, hyperlipidemia, and coronary artery disease) on treatment outcomes and the impact of treatment on other outcome measures such as quality of life require further study (Yao, 2022).
- A systematic review of nine studies (three randomized) revealed post-prostatectomy erectile dysfunction was sometimes more effectively treated by a combination of shock wave therapy and medication versus medication only. Authors agree that the literature is limited for shock wave therapy, and that studies are limited by small sample sizes, high risk of bias, and high heterogeneity (Sighinolfi, 2022).
- A systematic review/meta-analysis of seven studies showed shock wave therapy for erectile dysfunction, compared with vibration without energy transmission, was associated with higher scores using International Index of Erectile Function and Erectile Hardness Scale, both $P <.001$ (Liu, 2022).

- In patients with Peyronie's disease, a Cochrane review found very low to low certainty of evidence supporting any short-term effect of extracorporeal shock wave treatment on patients' self-reported ability to have intercourse, quality of life, or treatment-related adverse effects, or in the degree of penile curvature. No long-term data were available for any outcome (Rosenberg, 2023).

References

On September 30, 2024, 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," 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

12/2019: initial review date and clinical policy effective date: 1/2020

12/2020: Policy references updated.

12/2021: Policy references updated.

12/2022: Policy references updated.

12/2023: Policy references updated. Penile implants removed from policy, due to vendor criteria overlap.

12/2024: Policy references updated.