Transperineal laser ablation of the prostate for benign prostatic hyperplasia

Clinical Policy ID: CCP.1548

Recent review date: 10/1/2025

Next review date: 2/1/2027

Policy contains: Benign prostatic hyperplasia; EchoLaser X4; SoracteLite; Transperineal laser ablation.

First Choice VIP Care has developed clinical policies to assist with making coverage determinations. First Choice VIP Care's 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 First Choice VIP Care, 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. First Choice VIP Care's 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. First Choice VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice VIP Care will update its clinical policies as necessary. First Choice VIP Care's clinical policies are not guarantees of payment.

Coverage policy

Transperineal laser ablation of the prostate is investigational/not clinically proven and, therefore, not medically necessary for the treatment of benign prostatic hyperplasia.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Guideline-directed therapy (Lerner, 2023):

- Medical therapy, alone or in combination (alpha blockers, 5-alpha reductase inhibitors, phosphodiesterase-5 inhibitors).
- Transurethral resection of the prostate.
- Simple prostatectomy.
- Transurethral incision of the prostate
- Transurethral vaporization of the prostate.
- Photoselective vaporization of the prostate.
- Prostatic urethral lift.

- Water vapor thermal therapy.
- Laser enucleation.
- Robotic waterjet treatment.
- Prostate artery embolization.
- Temporary implanted prostatic devices.

Background

Benign prostatic hyperplasia, also known as benign prostatic hypertrophy, is a nonmalignant growth of prostate tissue and is relatively common in older individuals with a prostate. The condition is marked by symptoms of the lower urinary tract, urinary retention, or infections due to incomplete bladder emptying. Some cases will not require treatment but can be addressed by watchful waiting to ensure worsening of symptoms is limited. Other cases can be treated conservatively with alpha blockers, 5-alpha reductase inhibitors, phosphodiesterase-5 inhibitors, antimuscarinics, or a combination. However, these medications are not always effective and are associated with elevated risk of ejaculatory and erectile dysfunction (Ng, 2025).

For cases requiring surgery, transurethral approaches and enucleation procedures have largely replaced open prostatectomy as preferred surgical options. Minimally invasive surgical options such as transurethral microwave thermotherapy, water vapor or steam infusion therapy, and prostatic urethral internal lateral suturing have emerged, offering shorter time in the operating room, faster recovery, and fewer side effects (Ng, 2025).

Transperineal laser ablation of the prostate is an emerging treatment for benign prostatic hyperplasia associated with moderate-to-severe lower urinary tract symptoms. It is a minimally invasive, ultrasound-guided procedure that applies focused heat from a laser light into the prostate to ablate the enlarged tissue *in situ*. The laser forms an ellipsoidal area of coagulative necrosis, which the body resorbs. The procedure can be performed in an outpatient setting under local anesthesia (Sessa, 2022).

The U.S. Food and Drug Administration has issued 510(k) premarket clearance to the EchoLaser X4 (Elesta SpA, Calenzano, Italy). It is intended for necrotizing or coagulating soft tissue through interstitial irradiation for use in medicine and surgery, including urology, at a wavelength of 1064 nanometers (U.S. Food and Drug Administration, 2018, 2022). The manufacturer describes the EchoLaser as a “micro-invasive, multi-fiber” approach in which up to four flexible quartz optical fibers with a small diameter (300 micron) and a flat tip transmit laser light through fine 21-gauge needles inserted percutaneously. The procedure can be carried out with transrectal ultrasound guidance for real-time positioning and treatment monitoring. The device is also called SoracteLite™ when used specifically for urological indications, to differentiate from Echolaser thermal ablation used for other indications (Elesta-echolaser SpA, 2020).

Findings

Guidelines

No North American professional guidelines currently address transperineal laser ablation of the prostate for benign prostatic hyperplasia.

An interventional procedures guidance from the National Institute for Health and Care Excellence recommends transperineal laser ablation to treat lower urinary tract symptoms of benign prostatic hyperplasia in people who cannot have transurethral resection of the prostate or other transurethral procedures, and only with special arrangements for clinical governance, consent, and audit or research. In people who can have transurethral resection of the prostate or other transurethral procedures, more research is needed on the transperineal approach (National Institute for Health and Care Excellence, 2025).

Evidence review

The evidence of safety and effectiveness is summarized in two systematic reviews (Alberti, 2025, n = 702; Altieri, 2025; n = 717). The body of evidence included in these reviews consists of two small, randomized controlled trials comparing two prostate procedures — transperineal laser ablation and transurethral resection (Bertolo, 2023; Canat, 2023) — and several small, observational studies, each associated with a moderate-to-high risk of bias. One additional randomized controlled trial compared transperineal laser ablation to transurethral water vapor thermal therapy (Pacini, 2025; Zucchi, 2025). In all studies, the transperineal laser ablation procedure was performed with the EchoLaser X4 system.

Transperineal laser ablation is safe and feasible for relieving obstructive lower urinary tract symptoms, while sparing overall sexual function. Complication rates varied widely in individual studies, ranging from 0% to 65%. The most common complications were low-grade and transient (mainly Clavien-Dindo Grades I and II), such as transient dysuria and hematuria, hematospermia, urinary tract infections, and a few cases of acute urinary retention. No major complications were reported. Most patients were discharged on the same day, after a short post-operative observation period. Recovery was rapid, and while most studies had short follow-up periods, a few studies reported maintaining treatment effects up to a median of 12 months (Alberti, 2025; Altieri, 2025).

In the three small, randomized controlled trials directly comparing transperineal laser ablation to other transurethral procedures, the study populations represented participants mostly in their mid-sixties with severe lower urinary tract symptoms, obstructed urine flow, and mild to moderate erectile dysfunction impacting quality of life (Bertolo, 2023, n = 51; Canat, 2023, n = 25; Pacini, 2025 and Zucchi, 2025, both n = 80). Transperineal laser ablation provided significant short-term improvement in uroflow measurements, symptoms, and quality of life without compromising erectile or ejaculatory function and with a low risk of complications, while transurethral resection of the prostate offered superior improvement in uroflow measures but at a greater risk to sexual function (Bertolo, 2023; Canat, 2023). Compared to transurethral water vapor thermal therapy, transperineal laser ablation demonstrated comparable uroflow outcomes without compromising sexual function but slightly superior symptom resolution and quality of life improvement (Pacini, 2025; Zucchi, 2025).

There is no consensus on which patients would most benefit from this procedure, as there were no standardized inclusion criteria. Most study participants had medical therapy with no wash-out period before the procedure, and studies included those eligible and ineligible for transurethral resection of the prostate. Median/mean age varied widely, as did median/mean prostate volumes (ranging from 38 cc to 102 cc across studies). Studies were inconsistent in excluding patients with an obstructive median lobe or indwelling/intermittent catheters, although patients with anatomical or functional alterations that can impact bladder function or with a history of rectal surgery were generally excluded. Studies showed high heterogeneity ($I^2 > 85\%$ for most outcomes), suggesting considerable variability in the treatment effects across studies (Alberti, 2025; Altieri, 2025).

According to the systematic review investigators, the patients most likely to benefit appear to be those with medium-sized prostates who want to relieve obstructive symptoms without compromising sexual function and those who wish to avoid the risks associated with general anesthesia and hospitalization. Further research is needed to address long-term effectiveness and the patient-specific or intervention-related factors contributing to the variability in outcomes. This information will provide more robust findings that are comparable in quality to the evidence supporting resection or enucleation procedures considered the standard of care (Alberti, 2025; Altieri, 2025).

Two registry studies are in progress to assess long-term outcomes, with follow-up periods of five years. The estimated completion dates are January 2034 (ClinicalTrials.gov identifier NCT06564415) and February 2029 (ClinicalTrials.gov identifier NCT03776006).

References

On 8/8/2025, 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 “prostatic hyperplasia” (MeSH), “laser therapy” (MeSH), “Lower Urinary Tract Symptoms/surgery” (MAJR), “transperineal laser ablation,” “SoracteLite,” “transperineal laser ablation,” and “prostate.” 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

10/1/2025 initial review date and clinical policy effective date: 11/1/2025