Prostatic urethral lift/UroLift for benign prostatic hyperplasia

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Recent review date: 8/2025

Next review date: 12/2026

Policy contains: benign prostatic hyperplasia; prostatic urethral lift; UroLift.

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Coverage policy

Prostatic urethral lift (UroLift®, Teleflex, Inc., Pleasanton, California) is clinically proven and, therefore, may be medically necessary for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia when all of the following criteria are met (American Urological Association [Lerner, 2023]):

- Member has a prostate volume between 30 and 80 cc.
- There is verified absence of an obstructive median lobe of the prostate.

Limitations

For members with a prostate volume greater than 80 cc and up to 100 cc or with an obstructive median lobe, the decision to proceed with a prostatic urethral lift procedure should be made on a case-by-case basis, understanding the limited evidence supporting improved patient outcomes in these populations.

Contraindications to UroLift include the following (U.S. Food and Drug Administration, 2025):

- Prostate volume of >100 cc.

- A urinary tract infection.
- Urethral conditions that may prevent insertion of delivery system into bladder.
- Urinary incontinence.
- Current gross hematuria.
- A known allergy to nickel.

Alternative covered services

- Medications, including alpha blockers, 5-alpha reductase inhibitors, or a combination.
- Transurethral resection of the prostate.
- Guideline-directed minimally invasive surgery, including:
    - Convective radiofrequency water vapor thermal therapy
    - Prostatic arterial embolization
    - Temporary implantable nitinol device
    - Transurethral microwave thermotherapy

Background

Benign prostatic hyperplasia, also known as benign prostatic hypertrophy, is a nonmalignant growth of prostate tissue and relatively common in older people 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 (tadalafil), antimuscarinics, or a combination. However, these medications are not always effective and are associated with elevated risk of ejaculatory and erectile dysfunction (Ng, 2024).

For cases requiring surgery, transurethral approaches and enucleation procedures have largely replaced open prostatectomy as preferred surgical options. Minimally invasive surgical options such as paclitaxel-coated prostatic balloon dilation, transurethral microwave thermotherapy, water vapor or steam infusion therapy, and prostatic urethral internal lateral suturing (prostatic urethral lift) have emerged, offering shorter operating room time, faster recovery, and fewer side effects (Ng, 2024).

The prostatic urethral lift is an endoscopic procedure that retracts obstructing prostatic lobes using small metal implants to secure the retracted position of the enlarged prostate tissue away from the urethra. A disposable cartridge delivers an implant consisting of a capsular nitinol tab and a urethral stainless steel tab held together by a non-absorbable suture, which draws the prostatic urethra to the capsule. The procedure creates an open channel from the bladder neck to the verumontanum. It requires three to four tabs per implantation and either local or general anesthesia, and it can be performed in inpatient or outpatient settings (Rahman, 2024).

In 2013, the U.S. Food and Drug Administration approved the UroLift System UL400 for the treatment of benign prostatic hyperplasia in patients age 50 years and older with no obstructive median or lateral lobe hyperplasia and prostate volumes between 30 and 80 cc (U.S. Food and Drug Administration, 2013). In 2017, approval was expanded to include the UL500 model for lateral and median lobe prostate hyperplasia (U.S. Food and Drug Administration, 2017).

In 2019, approval for recent models expanded based on substantial equivalence to predicate devices and unpublished data presented to the U.S. Food and Drug Administration. Approval includes individuals with prostate volumes up to 100 cc and patients aged 45 years and older. Lowering the age criterion was based on an early American Urological Association guideline defining the index patient > 45 years of age with lower urinary tract symptoms and multiple studies demonstrating minimal differences between the populations age 45 and age 50 in terms of histopathology, volume, and symptomatology (U.S. Food and Drug Administration, 2025).

Findings

Guidelines

The American Board of Urology reports that prostatic urethral lift procedures increased significantly since its introduction in 2015, and currently account for one-third of all procedures for benign prostatic hyperplasia (Zhang, 2023).

According to the American Urological Association, the overwhelming majority of patients with lower urinary tract symptoms/ benign prostatic hyperplasia who desire treatment will choose some form of medical therapy, but medical therapy failure is not an absolute requirement for interventional procedures. The Association recommends surgery for patients who have: renal insufficiency, refractory urinary retention, or gross hematuria secondary to benign prostatic hyperplasia; recurrent urinary tract infections; recurrent bladder stones; lower urinary tract symptoms/ benign prostatic hyperplasia refractory to other therapies; or an unwillingness to use other therapies. While it is appropriate to discuss medical therapy with patients for whom additional therapy is warranted, proceeding to a procedural intervention without trialing medications may also be discussed as part of the informed decision-making process (Lerner, 2023).

The American Urological Association guideline recommends prostatic urethral lift for patients with lower urinary tract symptoms from benign prostatic hyperplasia who meet the following criteria (Lerner, 2023):

- Prostate volume is 30 to 80 cc and verified absence of an obstructive median lobe. For men with prostate sizes ranging from 81 to 100 cc or with obstructive median lobes, there was insufficient evidence to make formal recommendations.
- The patient desires preservation of erectile and ejaculatory function.

The American Urological Association's recommendations were based on the inclusion criteria and results of the L.I.F.T. study (ClinicalTrials.gov identifier NCT01294150). The inclusion criteria were participants aged 50 years and older with an International Prostate Symptom Score > 12, a peak flow rate (Qmax) ≤ 12 mL/s, and a prostate volume 30 to 80 cc. Participants were randomized to the Lift procedure or sham control and followed for five years. Prostatic urethral lift offered rapid improvement in symptoms, quality of life, and flow rate durable to five years with a higher likelihood of preserving sexual function compared to many other surgical interventions (Roehrborn, 2017).

A National Institute for Health and Care Excellence guideline on UroLift is similar to that of the American Urological Association, and recommends the procedure be reserved for patients 50 years and older (National Institute for Health and Care Excellence, 2021).

A European Association of Urology guideline resembles the American Urological Association in its recommendations for urethral lift for lower urinary tract symptoms in those with a prostate volume of < 70 cc and no middle lobe who are interested in preserving ejaculatory function (Cornu, 2024).

A Canadian Urological Association guideline recommends prostatic urethral lift for patients with lower urinary tract symptoms interested in preserving ejaculatory function with prostate volume < 80 cc, or for patients with a small to moderate median lobe and bothersome lower urinary tract symptoms (Elterman, 2022).

Evidence review

Recent systematic reviews/meta-analyses produced the following findings on the effectiveness of prostatic urethral lift/UroLift. While the prostatic urethral lift improves symptoms from a risk-benefit perspective, it is generally not as effective as transurethral resection of the prostate (Cornu, 2023). Similarly, Franco (2021, 2022), in a Cochrane review of 27 studies (n = 3,017), concluded that prostatic urethral lift showed little to no difference

in urological symptom improvement compared to transurethral resection of the prostate, although it was the most efficacious among five minimally invasive procedures.

Current evidence supports prostatic urethral lift/UroLift for patients with small prostate volumes ranging from 30 to 80 cc without obstructive median lobes based on the L.I.F.T. randomized, sham-controlled trial. The evidence for those with larger prostate volumes (81 to 100 cc) and with obstructive median lobes is very limited in the published literature. Results of the MedLift prospective, nonrandomized study (n = 45) were promising but insufficient to support prostatic urethral lift as a safe and effective treatment for patients with benign prostatic hyperplasia and obstructive median lobes (Rukstalis, 2019; ClinicalTrials.gov identifier: NCT02625545).

Long-term effectiveness and safety

The long-term effectiveness and safety of prostatic urethral lift have been highlighted in several studies. Jing (2020) observed that the effects of prostatic urethral lift weaken over time, with patients tracked up to 24 months, and that while it was not as effective as transurethral resection of the prostate, prostatic urethral lift remained safe and effective in selected patients. Tanneru (2020) supported these findings, reporting that prostatic urethral lift was well-tolerated and provided favorable outcomes in symptoms and sexual health over a 24-month period. Sajan (2022) noted that prostatic urethral lift had similar symptom improvement and adverse event rates compared to other minimally invasive procedures at three, six, and 12 months, but transurethral resection of the prostate consistently yielded superior outcomes during these periods.

A meta-analysis by Xiang (2020) consolidated data from 19 articles, covering 11 independent patient series and a total of 304 to 605 patients. The study found significant improvements in the International Prostate Symptom Score by 9.73 to 12.16 points, the Benign Prostatic Hyperplasia Impact Index by 3.74 to 4.50 points, and the maximum flow rate by 3.44 to 4.26 milliliters per second over 24 months. Quality of life scores also improved by 2.20 to 2.55 points, with stable or slightly improved sexual function. Complications were minimal and typically mild, with no significant changes in postvoid residual volume, supporting prostatic urethral lift as an effective and safe procedure that preserves sexual function.

Re-intervention rates and cost effectiveness

Re-intervention rates and cost effectiveness are critical factors in evaluating the overall utility of prostatic urethral lift. Miller (2020) analyzed data from 11 studies involving 2,016 patients and found a pooled annual surgical re-intervention rate of 6.0%, with variations depending on follow-up duration. This highlights a higher re-intervention rate than commonly cited in the literature, emphasizing the need for long-term follow-up data. Chughtai (2022) noted that prostatic urethral lift had lower improvements in prostate scores than other procedures and the highest five-year cost, approximately $9,580 compared to $6,328 for transurethral resection of the prostate. Despite these costs, Light (2021) found that prostatic urethral lift had the highest rate of erectile function preservation at one, six, 12, and 24 months compared with other minimally invasive procedures.

Comparative effectiveness of prostatic urethral lift and other treatments

Several studies have compared the effectiveness of prostatic urethral lift with other treatments over varying periods. Baboudjian (2023) reported that after five years, the effectiveness of surgical or minimally invasive retreatment was 13% for prostatic urethral lift versus 4% for water vapor thermal therapy. Lucas-Cava (2023) found that prostatic urethral lift had a significantly higher rate of re-interventions but a significantly lower rate of major adverse events compared to transurethral resection of the prostate. Minimally invasive procedures such as prostatic urethral lift did not result in significant changes in ejaculatory or erectile function and was associated with a lower risk of retrograde ejaculation compared to transurethral resection of the prostate, other electrosurgical procedures, and laser treatment (Busetto, 2025; Gemma, 2024; Manfredi, 2022). Page (2021) noted that after prostatic urethral lift, the in-hospital complication rate was 3.4%, with 93% of patients being catheter-free within 30 days, and re-treatment rates at one and two years were 5.2% and 11.9%, respectively.

In 2024, we revised the coverage section based on updated clinical guidelines from American Urological Association. We also revised the findings section to group studies thematically. We also added new systematic reviews (Miller, 2020; van Kollenburg, 2023; Xiang, 2020).

In 2025, we updated the references and revised the medical necessity criteria to align with current American Urological Association guideline recommendations for prostatic urethral lift procedures. These changes include deleting the age criterion and the requirement of medication failure.

References

On April 21, 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 “benign prostatic hyperplasia,” “benign prostatic hypertrophy,” “prostatic urethral lift,” and “UroLift.” 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

7/2023: initial review date and clinical policy effective date: 8/2023

7/2024: Policy references updated.

8/2025: Policy references updated. Coverage modified.