

Prostatic urethral lift/UroLift for benign prostatic hypertrophy

Clinical Policy ID: CCP.1529

Recent review date: 7/2024

Next review date: 11/2025

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

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Coverage policy

Prostatic urethral lift (UroLift) is clinically proven and, therefore, may be medically necessary for treatment of lower urinary tract symptoms due to benign prostatic hypertrophy/hyperplasia when all of the following criteria are met:

- Members age 50 and older
- Members with prostate volume between 30 and 80 grams (Sandhu, 2024) .
- Members with an absence of the median lobe of the prostate (Sandhu, 2024).
- Members who have failed treatment with medications (Cornu, 2023b; Lerner, 2021a; Lerner, 2021b; National Institute for Health and Care Excellence, 2021).

Limitations

Prostatic urethral lift (UroLift) is investigational/not clinically proven and, therefore, not medically necessary for any of the following:

- Prostate volume of >100 milliliters.
- A urinary tract infection.
- Urethra conditions that may prevent insertion of delivery system into bladder.
- Urinary incontinence.

- Current gross hematuria.
- A known allergy to nickel (U.S. Food and Drug Administration, 2013).

Alternative covered services

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

Background

Benign prostatic hypertrophy, also known as hyperplasia, is relatively common in older people with a prostate. The condition is marked by symptoms of the lower urinary tract. 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, or a combination. However, these medications are not always effective, and are associated with elevated risk of ejaculatory and erectile dysfunction (Garcia, 2015).

For cases requiring surgery, transurethral resection of the prostate has long been the preferred approach. Over time, efforts to develop less invasive procedures — which offer shorter operating room time, faster recovery, and fewer side effects — have been made. Transurethral needle ablation of the prostate and transurethral microwave thermotherapy are two such procedures, but both have been used less frequently over time.

Among the more recent less invasive procedures is prostatic urethral lift, which retracts obstructing prostatic lobes. The procedure begins with a cystoscopy to inspect the bladder neck and prostate, especially the middle and lateral lobes. 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 a channel from the bladder neck to the verumontanum (Garcia, 2015).

One end of an implant is attached to the surface of the prostatic capsule, and the other end is inside the urethra. The procedure typically uses about four implants to widen the urethra. The procedure is performed under local or general anesthesia, usually in an outpatient setting (National Institute for Health and Care Excellence, 2021).

In 2013, the U.S. Food and Drug Administration gave approval to the UroLift System UL400 (NeoTract Inc., Pleasanton, CA) for the use of UroLift for benign prostatic hyperplasia in patients older than 45 years (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).

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

Findings

An American Urological Association guideline recommends prostatic urethral lift for patients with urinary tract symptoms from benign prostatic hypertrophy under certain conditions:

- Prostate volume is 30 to 80 grams.
- An absence of an obstructive median lobe is verified.
- The patient desires preservation of erectile and ejaculatory function (Lerner, 2021a, 2021b, Sandhu, 204).

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 milliliters and no middle lobe who are interested in preserving ejaculatory function (Cornu, 2023a).

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 milliliters, or for patients with a small to moderate median lobe (Elterman, 2022).

In a 2022 review article, researchers used the Appraisal of Guidelines for Research and Evaluation II tool, which is a validated instrument designed to assess the methodological rigor and transparency of clinical practice guideline development, to evaluate the quality of guidelines from the European Association of Urology, American Urological Association, and National Institute for Health and Care Excellence on surgical and minimally invasive treatments for benign prostatic hyperplasia (Dmitry, 2022). While the guidelines generally scored well, the analysis raised concerns about low scores in the stakeholder involvement and applicability domains, suggesting the guidelines do not sufficiently incorporate patient views, clearly define target users, specify implementation barriers, or provide audit criteria (Dmitry, 2022).

Recent systematic reviews/meta-analyses produced the following findings on the effectiveness (outcomes) of prostatic urethral lift/UroLift:

Effectiveness of Prostatic Urethral Lift

While prostatic urethral lift improves symptoms from a risk-benefit perspective, it is generally not as effective as transurethral resection of the prostate. Cornu (2023b) found that prostatic urethral lift outcomes were less effective overall when compared to transurethral resection of the prostate. 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.

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. Sajjan (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.

Specific Outcomes and Comparison with Other Treatments

Detailed analyses of specific outcomes further illuminate the comparative effectiveness of prostatic urethral lift. A meta-analysis by Xiang et al. (2020) consolidated data from 19 articles, covering 11 independent patient series and a total of 304-605 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 et al. (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. Manfredi (2022) observed that prostatic urethral lift did not result in significant changes in ejaculatory or erectile function and was associated with a lower risk of retrograde ejaculation. 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).

References

On June 12, 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 benign prostatic hyperplasia; benign prostatic CCP.1529

hypertrophy; prostatic urethral lift; 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.

Baboudjian M, Cornu J-N, Gondran-Tellier B, et al. Pharmacologic and surgical retreatment after office-based treatments for benign prostatic hyperplasia: A systematic review. *Eur Urol Focus*. 2023;S2455-4569(23)00066-4. Doi: 10.1016/j.euf.2023.03.004.

Chughtai B, Rojanasart S, Neeser K, et al. A comprehensive analysis of clinical, quality of life, and cost-effectiveness outcomes of key treatment options for benign prostatic hyperplasia. *PLoS One*. 2022;17(4):e0266824. Doi: 10.1371/journal.pone.0266824.

Cornu J-N, Gacci M, Hashim H, et al. EUA Guidelines on Non-Neurogenic (Male) Lower Urinary Tract Symptoms (LUTS) Inc. Benign Prostatic Obstruction (BPO). <https://uroweb.org/guidelines/management-of-non-neurogenic-male-luts>. Last updated March 2023. (a)

Cornu J-N, Zantek P, Burt G, et al. Minimally invasive treatments for benign prostatic obstruction: A systematic review and network meta-analysis. *Eur Urol*. 2023;83(6):534-547. Doi: 10.1016/j.eururo.2023.02.028. (b)

Elterman D, Aube-Peterkin M, Evans H, et al. UPDATE – Canadian Urological Association guideline: Male lower urinary tract symptoms/benign prostatic hyperplasia. *Can Urol Assoc J*. 2022;16(8):245-256. Doi: 10.5489/cuaj.7906.

Enikeev D, Misrai V, Rijo E, et al. EAU, AUA and NICE Guidelines on surgical and minimally invasive treatment of benign prostate hyperplasia: A critical appraisal of the guidelines using the AGREE-II tool. *Urologia Internationalis*. 2021;106(1):1-10. Doi: 10.1159/000517675.

Franco JV, Jung JH, Imamura M, et al. Minimally invasive treatments for lower urinary tract symptoms in men with benign prostatic hyperplasia: A network meta-analysis. *Cochrane Database Syst Rev*. 2021;7(7):CD013656.

Franco JVA, Jung JH, Imamura M, et al. Minimally invasive treatments for benign prostatic hyperplasia: A Cochrane network meta-analysis. *BJU Int*. 2022;130(2):142-156. Doi: 10.1111/bju.15653.

Garcia C, Chin P, Rashid P, Woo HH. Prostatic urethral lift: A minimally invasive treatment for benign prostatic hyperplasia. *Prostate Int*. 2015;3(1):1-5. Doi: 10.1016/j.pnrl.2015.02.002.

Jing J, Wu Y, Du M, et al. Urethral lift as a safe and effective procedure for prostatic hyplasia population: A systematic review and meta-analysis. *Front Surg*. 2020;7:598728. Doi: 10.3389/fsurg.2020.598728.

Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I – Initial work-up and medical management. *J Urol*. 2021;206(4):806-817. Doi: 10.1097/JU.0000000000002183. (a)

Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I – Surgical Evaluation and Treatment. *J Urol*. 2021;206(4):818-826. Doi: 10.1097/JU.0000000000002184. (b)

Light A, Jabarkhyal D, Gilling P, et al. Erectile function following surgery for benign prostatic obstruction: A systematic review and network meta-analysis of randomized controlled trials. *Eur Urol*. 2021;80(2):174-187. Doi: 10.1016/j.eururo.2021.04.012.

Lucas-Cava V, Sanchez-Margallo FM, Gorbea II, Sun F. Comparative efficacy and safety of prostatic urethral lift vs prostatic artery embolization for benign prostatic hyperplasia: A systematic review and network meta-analysis. *BJU Int*. 2023;131(2):139-152. Doi: 10.1111/bju.15748.

Manfredi C, Garcia-Gomez B, Arcaniolo D, et al. Impact of surgery for benign prostatic hyperplasia on sexual function: A systematic review and meta-analysis of erectile function and ejaculatory function. *Eur Urol Focus*. 2022;8(6):1711-1732. Doi: 10.1016/j.euf.2022.06.007.

Miller LE, Chughtai B, Dornbier RA, McVary KT. Surgical reintervention rate after prostatic urethral lift: systematic review and meta-analysis involving over 2,000 patients. *J Urol*. 2020;204(5):1019-1026. Doi:10.1097/JU.0000000000001132.

National Institute for Health and Care Excellence. UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. MTG 58. <https://www.nice.org.uk/guidance/mtg58>. Published May 4, 2021.

Page T, Veeratterapillay R, Keltie K, Burn J, Sims A. Prostatic urethral lift (UroLift): A real-world analysis of outcomes using hospital episodes statistics. *BMC Urol*. 2021;21(1):55. Doi: 10.1186/s12894-021-00824-5.

Sajan A, Mehta T, Desai P, Isaacson A, Bagla S. Minimally invasive treatments for benign prostatic hyperplasia: Systematic review and network meta-analysis. *Vasc Interv Radiol*. 2022;33(4):359-367.e8. Doi: 10.1016/j.jvir.2021.12.029.

Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. *J Urol*. 2024;211(1):11-19. Doi: 10.1097/JU.0000000000003698. Tanneru K, Gautam S, Norez D, et al. Meta-analysis and systematic review of intermediate-term follow-up of prostatic urethral lift for benign prostatic hyperplasia. *Int Urol Nephrol*. 2020;52(6):999-1008. Doi: 10.1007/s11255-020-02408-y.

U.S. Food and Drug Administration. De Novo Classification Request for Neotract's UroLift System. https://www.accessdata.fda.gov/cdrh_docs/reviews/k130651.pdf. Published March 7, 2013.

U.S. Food and Drug Administration. 501(k) Premarket Notification. Implantable transprostatic tissue retractor system. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173087>. Published December 28, 2017.

van Kollenburg RAA, van Riel LAMJG, de Bruin DM, de Rijke TM, Oddens JR. Novel minimally invasive treatments for lower urinary tract symptoms: a systematic review and network meta-analysis. *Int Braz J Urol*. 2023;49(4):411-427. Doi:10.1590/S1677-5538.IBJU.2023.0016.

Xiang P, Wang M, Guan D, et al. A systematic review and meta-analysis of prostatic urethral lift for male lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Eur Urol Open Sci*. 2020;19:3-15. Doi:10.1016/j.euros.2020.05.001.

Zhang TR, Thorogood SL, Sze C. Current practice patterns in the surgical management of benign prostatic hyperplasia. *Urology*. 2023;S0090-4295(23)00191-7.

Policy updates

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

7/2024: Policy references updated.