

Prostatic urethral lift/UroLift for benign prostatic hypertrophy

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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 milliliters
- Members with an absence of the median lobe of the prostate
- 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 not clinically proven, and therefore investigational, 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 milliliters.
- An absence of an obstructive median lobe is verified.
- The patient desires preservation of erectile and ejaculatory function (Lerner, 2021a, 2021b).

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).

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

- (63 studies) After prostatic urethral lift, symptoms improved from a risk-benefit perspective, but overall outcomes were not as effective as transurethral resection of the prostate (Cornu, 2023b).
- (36 studies, n = 6,380) After five years, the effectiveness of surgical/minimally invasive retreatment was 13% for UroLift versus 4% for water vapor thermal therapy (Baboudjian, 2023).
- (8 studies, n = 675) Prostatic urethral lift, compared with transurethral resection, had a significantly higher rate of re-interventions, but a significantly lower rate of major adverse events (Lucas-Cava, 2023).
- (48 studies, n = 5,035) After prostatic urethral lift, no significant changes occurred in ejaculatory/erectile function, and minimally invasive surgery could be linked with lower risk of retrograde ejaculation (Manfredi, 2022).

- (27 studies, n = 3,017, Cochrane) Prostatic urethral lift had little to no difference in urological symptom improvement versus transurethral resection, but was the most efficacious of five minimally invasive procedures (Franco, 2021, 2022).
- Prostatic urethral lift had similar symptom improvement/adverse event rate versus other minimally invasive procedures at three, six, and 12 months. Transurethral resection had superior outcomes in each time period (Sajan, 2022).
- (47 studies) Urethral lift had lower improvements in prostate scores than other procedures, and had the highest five-year cost (e.g., \$9,580 versus \$6,328 compared to transurethral resection) (Chughtai, 2022).
- (48 studies, n = 5,159) Urethral lift had the highest rate of erectile function at one, six, 12, and 24 months compared with other minimally invasive procedures (Light, 2021).
- (n = 2,942) After UroLift, the in-hospital complication rate was 3.4%, while 93% of patients were catheter-free within 30 days. Re-treatment rates at one and two years were 5.2% and 11.9% (Page, 2021).
- (11 studies, n = 1,443) Effects of prostatic urethral lift weaken over time (patients were tracked at 24 months); not as effective as transurethral resection; UroLift is safe and effective in selected patients (Jing, 2020).
- (5 studies, n = 322) After 24 months, prostatic urethral lift was well-tolerated and provided favorable outcomes in symptoms, sexual health, and outcomes (Tanneru, 2020).

References

On May 24, 2023, 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; 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.

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, Jabarkhyl 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.

National Institute for Health and Care Excellence. UroLift for treating lower urinary tract symptoms of benign prostatic hypertrophy. 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.

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.

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

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