



**Kaiser Foundation Health Plan
of Washington**

**Clinical Review Criteria
Prostatic Urethral Lift (PUL or UroLift)**

- For the treatment of benign prostatic hyperplasia (BPH)

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**Criteria
For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Local Coverage Article: Urolift (A54044) Noridian retired Local Coverage Article (LCA) Urolift (A54044). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or a LCD. Most LCAs are not retired because they are incorrect. Therefore, continue to use LCA A54044 for determining medical necessity.

For Non-Medicare Members

Covers prostatic urethral lift (e.g., UroLift) as medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when **ALL of the following** criteria are met:

- age 50 or above
- prostate volume < 80 cc on ultrasound imaging
- no obstructive median lobe of the prostate identified on cystoscopy
- failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g., at least one drug trial from one of the following categories: alpha blocker, PDE5 inhibitor, finasteride/dutasteride)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Benign prostatic hyperplasia (BPH) is most common among men between 50 to 60 years old. BPH growth is associated with aging and varies from person to person. The doubling time of BPH growth is 4.5 years and 10 years between the ages of 31- 50 and 51 to 70 respectively [1]. Although the exact etiology is not well known, BPH is characterized by an augmentation of epithelial and stroma cells in the periurethral region of the prostate [1] resulting in a compression of the wall of the urethra and a decrease of the urine flow. Men with BPH present with low urinary tract symptoms (LUTS), including urinary frequency, urgency, intermittency, hesitancy, nocturia, straining, incomplete emptying, or weak urinary stream [2]. These conditions compromise erectile function and result in low quality of life (QOL) and depression. BPH are generally evaluated by using one of the following scores: the American

Urological Association Symptom Index (AUASI) and the International Prostate Symptoms Score (IPSS). AUASI is a self-administered questionnaire with symptoms scores ranging from 0 to 35 with higher scores (>20) equivalent to severe symptoms. The IPSS includes AUASI and QOL questions [1].

Various management options are available for BPH symptoms. These include watchful waiting, surgery, radiation, and medication such as α -1 blockers, 5- α - reductase inhibitors, antimuscarinics, beta-3 adrenoreceptor agonists or phosphodiesterase-5 inhibitors (PDE5i). Surgery, which is recommended in case of complications or if medical management fails, consists of transurethral resection of the prostate (TURP) and has been associated with various adverse events affecting erectile function and QOL [1]. However, Prostatic Urethral Lift (PUL or UroLift), a novel therapeutic approach is believed to conserve erectile function.

The Prostatic Urethral Lift (UroLift) is a minimally invasive procedure that provides anterolateral mechanical traction of the lateral lobes of the prostate, reducing obstruction and opening the urethral lumen. The procedure is carried out transurethrally under local or general anesthesia [3]. The system is composed of a UroLift Delivery Device and a UroLift Permanent Implant. The UroLift Delivery Device is positioned through the obstructed urethra to access and compress one lateral lobe of the prostate toward the capsule. The implant, made with nitinol, stainless steel urethral end piece and polyethylene terephthalate suture (PET), is attached in the urethra and the other end anchored to the outer part of the prostatic capsule, retracting the prostatic lobe and liberating the urethral lumen. The procedure is performed endoscopically with minimal incision or thermal injury of the prostate. Multiple implants can be introduced during each procedure [3].

The Prostatic Urethral Lift was approved by the Food and Drug Administration (FDA) in 2013 and is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above. The technology has not been reviewed previously by MTAC. It is being reviewed for the first time based on a request from the Clinical review Unit for coverage decision.

Medical Technology Assessment Committee (MTAC)

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)

03/21/2016: MTAC REVIEW

Evidence Conclusion: **Conclusion from INTC review** - "Urolift may be viable alternative to TURP for patients with LUTS secondary to BPH. Short-term data from low to moderate quality, industry-funded studies conclude that Urolift is effective and safe. The overall quality of the evidence is low to moderate. However, due to concerns regarding risk of bias in these studies, a definitive conclusion regarding the long-term safety and effectiveness of UroLift cannot be made from existing evidence. Additional, high quality studies with longer follow-up are needed to confirm preliminary findings".

Articles: Since the search did not identify new studies, and because INTC evidence review is recent, their review can be adopted. In addition, the search did not find studies comparing PUL to medical management. [See Summary of RCTs.](#)

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)

06/28/2017: MTAC REVIEW

Evidence Conclusion: One study (C Roehrborn et al., 2016) ([See Evidence Table 1](#)) assessed the long term (4 years) effectiveness and safety of PUL. PUL was compared to sham control. Characteristics of patients were similar. Patients were randomized to either PUL (N=140) or sham control (N=66) at 19 centers in North America and Australia, and followed for 4 years. The authors reported that Urolift improved urinary symptoms, preserved sexual and ejaculatory function with minor adverse events. The authors indicated that durability of these effects needs to be confirmed at 5-year follow-up. The risk of bias is unclear for incomplete outcome data and the major limitation is the high attrition rate. The author of the previous study (Claus Roehrborn et al., 2017) ([See Evidence Table 2](#)) confirmed the durability of PUL effects in the 5-year follow-up study. Urinary symptoms (IPSS), BPHII, flow rate (Qmax), QoL, erectile and ejaculation functions were improved and /or preserved with minimal complications. Another abstract was reviewed (Henry Woo). Comparison was made between PUL and sham. This was a crossover study wherein 53 patients were enrolled. Patients were treated with sham, then crossover occurred and patients were followed for 4 years. Compared to baseline, IPSS, QoL, and BPHII statistically improved at 45%, 49%, and 44% respectively (P<0.001). Flow rate (Qmax) also increased by 50% (P=0.01). Adverse events were mild. Level of evidence: In the first two studies, the risk of bias is unclear for incomplete outcome data and low in other domains of risk of bias assessment; no serious precision or directness issues were identified; findings were consistent; the quality of the

study assessed by Modified Jadad Scale is high. The studies provide moderate evidence to support the use of PUL. Conclusion:

- The long-term effectiveness and safety is based on three articles that compare PUL versus sham over 4 and 5 years. Compared to sham, moderate level of evidence indicates that PUL is effective and durable in patients with LUTS due to BPH on the long-term.
- The technology is also safe with minimal complications.

Articles: Three articles were reviewed: Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalis, D. (2016). Prospective, randomised, blinded study of Prostatic Urethral Lift (pul): four year results. BJU Int, 117, 19-20. Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Te, A. (2017). PD27-01 5 year prospective, randomized, controlled study results on the minimally invasive prostatic urethral lift (PUL). J Urol, 197(4), e511. Crossover study on the prostatic urethral lift (pul): 4 year results. Henry Woo, Sydney, Australia; Jack Barkin, Toronto, Canada; Damien Bolton, Heidelberg, Australia; Prem Rashid, Port Macquarie, Australia; Anthony Cantwell, Daytona Beach, FL; William Bogache, Myrtle Beach, SC; Stephen Richardson, Salt Lake City, UT; Ronald Tutrone, Baltimore, MD; James Fagelson, Englewood, CO; Peter Chin, Figtree, Australia

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Date Created	Date Reviewed	Date Last Revised
03/21/2016	04/05/2016 ^{MPC} , 02/07/2017 ^{MPC} , 08/01/2017 ^{MPC} , 09/05/2017 ^{MPC} , 08/07/2018 ^{MPC}	08/01/2017

^{MPC} Medical Policy Committee

Revision History	Description
04/05/2016	Created criteria; added MTAC review
08/01/2017	Added 6/2017 MTAC review
09/18/2017	Added LCA retirement language

Codes

CPT – 52441, 52442
 HCPC – C9739, C9740