Health Evidence Review Commission (HERC)

Coverage Guidance:

Prostatic Urethral Lift for

Treatment of Benign Prostatic Hypertrophy

Approved 5/17/2018

HERC Coverage Guidance

The Prostatic Urethral Lift procedure is recommended for coverage *(strong recommendation)* for treatment of men with symptomatic benign prostatic hypertrophy when the following criteria are met:

- Age 50 or older
- Estimated prostate volume < 80 cc
- IPSS score ≥ 13
- No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure
- Failure, contraindication, or intolerance to at least three months of conventional medication therapy for benign prostatic hypertrophy

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Informed Framework Element Description*.

Oregon Health Authority

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness may be dependent on the environment in which the intervention is implemented.

GRADE-Informed Framework

HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy (CEbP).

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from CEbP. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of HERC.

Should prostatic urethral lift be recommended for coverage for benign prostatic hypertrophy with lower urinary tract symptoms?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Quality of life *(Critical outcome)*	PUL is associated with a standard mean gain in health-related quality of life of -2.2 (95% CI -2.4 to -2.1) (negative values represent improvement). ●●●○ *(Moderate confidence, based on 6 studies with 680 patients)* *Extended follow-up (5 years) of patients in an RCT of PUL found these improvements to be durable.*	When PUL is performed as an outpatient procedure under local anesthesia, cost savings are significant as compared with TURP (given that procedural complication rates are similar or lower).	Most men with symptomatic BPH would value surgical intervention that is less invasive and less costly than TURP, if the alternative procedure has similar effectiveness and a similar or	
Need for re-operation *(Important outcome)*	1.5% to 16% of patients will undergo TURP within 12 months of the PUL procedure. ●●○○ *(Low confidence, based on 6 studies with 680 patients)*			

Should prostatic urethral lift be recommended for coverage for benign prostatic hypertrophy with lower urinary tract symptoms?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Procedural complications *(Important outcome)*	For the direct comparison of PUL and TURP, Clavien-Dindo grade 1 adverse events occurred in 68% of PUL patients and 74% of TURP patients (p = 0.6); Clavien-Dindo grade 2 or 3 adverse events occurred in 16% and 22% of patients respectively. ●○○○ *(Very low confidence, based on 1 RCT with 80 patients)*	PUL cost savings are moderated by the low but significant rate of subsequent requirement for TURP, however. Cost modeling studies performed for NICE showed that PUL is cost saving compared with TURP (if used in a day surgery unit).	lower rate of procedural complications. We would expect low variability in this preference, although some men would still prefer TURP as a more definitive and better established procedure.	
Long-term harms *(Important outcome)*	For the direct comparison of PUL and TURP, erectile function was similar at 2 years in both arms: 98% of PUL patients and 94% of TURP patients met the erectile function criterion; ejaculatory function at 2 years was preserved in 100% of PUL patients compared to 34% of the TURP patients. For the direct comparison of PUL and TURP, urinary incontinence was more likely in the TURP arm at 2 weeks and 3 months of follow-up, but did not significantly differ between the groups at 12 or 24 months follow-up. ●○○○ *(Very low confidence, based on 1 RCT with 80 patients)*			
Change in prostate symptom scores *(Important outcome)*	PUL is associated with a standard mean gain in prostate symptom scores of -1.5 (95% CI -1.6 to -1.3) (negative changes represent improvement). ●●●○ *(Moderate confidence, based on 6 studies with 680 patients)* *Extended follow-up (5 years) of patients in an RCT of PUL found these improvements to be durable.*			

Should prostatic urethral lift be recommended for coverage for benign prostatic hypertrophy with lower urinary tract symptoms?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Balance of benefits and harms: Fair-quality RCTs utilizing PUL demonstrate small but consistent improvements in health-related quality of life and prostate symptom scores, findings in which we have moderate confidence. Symptomatic improvements have been shown to be durable in a 5-year RCT. Compared with TURP, PUL has similar procedural complication rates, but PUL appears to be much better in preservation of ejaculatory function at two years post-procedure. The balance of benefits and harms weighs in favor of PUL, but benefits are moderated by a subsequent need for TURP in 1.5% to 16% of patients within one year of PUL.				
Rationale: Our recommendation for coverage of PUL is based on consistent results in critical and important outcomes, demonstrating symptomatic improvement in lower urinary tract symptoms caused by BPH. Values and preferences, as well as resource allocation, weigh in favor of PUL as the less invasive, less costly outpatient procedure (compared with TURP). Our recommendation is strong because of the moderate strength of the evidence and positive balance of benefits and harms.				
Recommendation: The Prostatic Urethral Lift procedure is recommended for coverage *(strong recommendation)* for treatment of men with symptomatic benign prostatic hypertrophy when the following criteria are met: • Age 50 or older • Estimated prostate volume < 80 cc • IPSS score ≥ 13 • No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure • Failure, contraindication, or intolerance to at least three months of conventional medication therapy for benign prostatic hypertrophy				

Note: GRADE-informed framework elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

Background

Benign prostatic hyperplasia (BPH) is the nonmalignant growth of the prostate and typically starts at approximately 40 years of age and increases as men age (Roehrborn, 2005). Many men with histologic BPH will never consult a healthcare provider or receive treatment for the condition (Roehrborn, 2005). The most frequent manifestation of BPH is lower urinary tract symptoms, caused by the prostate putting pressure on the bladder or urethra and thus interfering with urine flow. Urinary symptoms include hesitancy, straining, weak flow, prolonged voiding, partial or complete urinary retention, nocturia, incontinence, and painful urination (Roehrborn, 2005).

The chart below shows the calculations to create the International Prostate Symptom Score (I-PSS). A score of 1 to 7 is categorized as Mild, 8 to 19 is Moderate, and 20 to 35 is Severe.

In the past month:	Not at all	Less than 1 in 5 times	Less than half the time	About half the time	More than half the time	Almost always	Score
1. Incomplete Emptying – How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5	
2. Frequency – How often have you had to urinate less than every two hours?	0	1	2	3	4	5	
3. Intermittency – How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
4. Urgency – How often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Weak Stream – How often have you had a weak urinary stream?	0	1	2	3	4	5	
6. Straining – How often have you had to strain to start urination?	0	1	2	3	4	5	
	None	1 time	2 times	3 times	4 times	5 times	
7. Nocturia – How many times did you typically get up at night to urinate?	0	1	2	3	4	5	
Total I-PSS Score							

Lower urinary tract symptoms caused by BPH are among the most common reasons for urologic consultation in clinical practice (Magistro et al., 2017). In the U.S., the annual expenditures on the management of lower urinary tract symptoms due to BPH are estimated at approximately $6 billion dollars (Magistro et al., 2017).

Treatments for BPH include conservative approaches, pharmacological options, and various surgical procedures. Side effects of pharmacological treatments can include postural hypotension, dizziness, asthenia, and compromised sexual function (Magistro et al., 2017). The most frequent form of surgery is monopolar or bipolar transurethral resection of the prostate (TURP), which uses transurethral electrosurgery to remove prostate tissue during irrigation (Ray et al., 2015). Refinements of the technique have improved the safety profile of TURP over time; however, the procedure causes considerable long-term complications including ejaculatory dysfunction (65%), erectile dysfunction (10%), urethral strictures (7%), urinary tract infection (4%), bleeding requiring transfusion (2%), urinary incontinence (2%), and the procedure has a retreatment rate of 6% (Magistro et al., 2017).

A more recent surgical intervention is prostatic urethral lift (PUL), sold under the trade name of UroLift®. The PUL system lifts and holds the enlarged prostate tissue to create a continuous anterior channel through the prostatic lumen extending from the bladder neck to the verumontanum (Magistro, 2017). The UroLift® System (PUL) received De Novo approval from the U.S. Food and Drug Administration (FDA) in 2013 (NeoTract, 2017).

Indications

The UroLift® System (PUL) is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to BPH in men 50 years of age or older. The contraindications include:

- Prostate volume of > 80 cc
- Obstructive or protruding median lobe of the prostate
- Urinary tract infection
- Urethra conditions that could prevent insertion of delivery system into bladder
- Urinary incontinence
- Current gross hematuria (NeoTract, 2017).

Technology Description

The PUL implantation procedure can be performed in an outpatient or inpatient setting and under general or local anesthesia, and the attending urologist completes comprehensive training prior to using the PUL system (NeoTract, 2017). The delivery device is used to compress one lateral lobe of the prostate toward the prostatic capsule. Then, a needle is used to deploy the implant, with one end of the implant anchored in the urethra and the other on the outer surface of the prostatic capsule, retracting the prostatic lobe away from the urethral lumen (Ray, 2015).

The permanent PUL implant is composed of a nitinol capsular tab (diameter: 0.6 mm, length: 8 mm), an adjustable polyethylene teraphtalate nonabsorbable monofilament (diameter: 0.4 mm), and a stainless steel urethral end piece (8 mm x 1mm x 0.5 mm). In most cases, no postinterventional catheterization is required (Magistro, 2017). Typically, four implants are placed (NeoTract, 2017).

Evidence Review

Perera et al., 2016

This is a fair-quality systematic review of six studies of PUL. The review includes one sham-controlled randomized controlled trial (RCT), one observational cohort that followed crossover patients from that RCT, two prospective cohorts, and two retrospective cohorts. These studies involved 680 patients. Results for most of the outcome measures were reported as standardized mean gains (which the authors noted can be interpreted as similar to Cohen's *d* statistic). In most of the included studies, patients were eligible if they were over age 50, had an IPSS greater than 12, and had prostate volumes estimated between 20 and 100 ml. Patients were excluded if they had obstructive median prostate lobes, urinary infections, acute urinary retention, or prostate-specific antigen (PSA) levels greater than 10 ng/ml. Most of the enrolled patients were between age 65 and 75, and the mean baseline IPSS was in the low to mid-20s. For meta-analytic results at the 12-month follow-up, the standard mean gain in health-related quality of life was -2.2 (95% CI -2.4 to -2.1), where negative scores reflect improvement; the standard mean gain in prostate symptom scores was -1.5 (95% CI -1.6 to -1.3); and the standard mean gain in male sexual health scores was 0.3 (95% CI 0.2 to 0.4). These effects on health-related quality of life and prostate symptom scores are conventionally regarded as large effect sizes. Among the included studies, the rate of insufficient improvement and progression to TURP ranged from 1.5% to 16% of patients at 12 months. Nearly all of the procedures were performed under local anesthesia. The most commonly reported complications in the first three months after the procedure were hematuria (16% to 75% of patients), dysuria (25% to 53% of patients), pelvic pain (3.7% to 19.3% of patients), urinary tract infection (3.2% to 10% of patients), and transient urinary incontinence (1.9% to 16% of patients). Overall, the authors concluded that the procedure is well tolerated with few periprocedural complications and is effective for improving quality of life, prostate symptom scores, and sexual function scores at up to 12 months.

Roehrborn et al., 2017

This is a fair-quality study of five-year outcomes from the prospective, randomized, sham-controlled, double-blind trial of the PUL. The study was performed at 19 centers in the United States, Canada, and Australia. Patients were eligible to enroll if they were age 40 or older, had IPSS ≥ 13, peak urinary flow rate ≤ 12 ml/s, and prostate volume between 30 cc and 80 cc as assessed by transrectal ultrasound. Patients were excluded if they had an obstructive median lobe or active urinary infection. Patients treated with alpha blockers or 5-alpha reductase inhibitors were required to stop these medications during a washout period (two weeks and three months, respectively). Ultimately, 206 patients were randomized (2:1) to PUL or cystoscopy with sham procedure. The groups had similar characteristics at baseline. Planned follow-up for the randomized access portion of the trial was three months, and patients and outcomes assessors were blinded during this period. After three months, patients in the sham control arm were unblinded and allowed to cross over to PUL (80% of sham control patients did so). About one-third of the patients experienced voiding dysfunction after the procedure and required a catheter for a mean duration of 0.9 days.

For the randomized comparison between groups at three months, there was greater improvement in quality of life in the PUL group (2.2 ± 1.8) than in the sham control group (1.0 ± 1.5) ($p < 0.001$). Similarly, there was greater improvement in IPSS in the PUL group (-11.1 ± 7.7) than in the sham control group (-5.9 ± 7.7) ($p = 0.003$).

At five years of follow-up, data were available for 104 of the original 140 patients (74.3%) in the PUL arm (of the 36 patients for whom data were incomplete, 18 were lost to follow-up, nine died, five sought treatment for cancer, and four underwent TURP or laser ablation). The overall rate of surgical retreatment at five years was 13.6%: six patients received additional PUL procedures and 13 patients received TURP. Intention-to-treat outcomes for the PUL arm (compared to baseline) at five years were calculated using the last observation carried forward. The mean change in IPSS at five years was -7.85, which reflects a 35% improvement from baseline. The mean change in quality of life at five years was -2.08, which reflects a 45% improvement from baseline. There was no significant change in sexual function compared to baseline in the per-protocol five-year follow-up among patients in the PUL arm.

Adverse effects were uncommon and most likely to occur in the first three months. Pelvic pain, dysuria, hematuria, and urge incontinence were the most common adverse events, occurring in 3% to 9% of patients. Other adverse effects occurred in less than 1% of patients.

CEbP staff noted that the study was limited by the absence of blinded, randomized follow-up beyond three months, the moderate loss to follow-up at five years, and the attendant use of last observation carried forward to estimate the durability of effects. Three of the authors disclosed conflicts of interest with NeoTract, the maker of the PUL system. This study was rated fair quality for these reasons.

Gratzke et al., 2017

This is a fair-quality RCT comparing PUL to TURP that was conducted at 10 centers in three European countries. Patients were eligible for inclusion if they were over age 50; were a candidate for TURP; and had IPSS > 12, a maximum urinary flow rate of 15 ml/s, and prostate volume < 60 cc by ultrasound. Patients were excluded if they had active urinary infection, had obstructive median lobe, had previously undergone TURP or laser ablation, or had a PSA >10 ng/l. Ninety patients were randomized (1:1) to undergo either PUL or TURP. Ten patients randomized to TURP declined treatment, and one patient randomized to PUL declined treatment; ultimately there were 35 patients in the TURP group and 45 patients in the PUL group. Patients were followed for two years. A variety of prostate symptom-specific measures and general quality of life measures were assessed. Baseline patient characteristics were not reported. The groups were generally similar at baseline, the mean age was approximately 64 years, and the mean IPSS was approximately 22.

At two years follow-up, IPSS and IPSS health-related quality of life had improved compared to baseline in both treatment arms. The change in IPSS was smaller in the PUL arm than the TURP arm (-9.2 vs. -15.3, p = 0.004). The change in IPSS health-related quality of life was similar between the PUL arm and the TURP arm (-3.3 vs. -2.5, p = 0.066). The proportion of patients achieving a minimal clinically important difference in quality of life as measured by the SF-6D utility score was similar at two years (47% in the PUL arm vs. 37.5% in the TURP arm, p = 0.43). Erectile function was similar at two years in both arms: 98% of PUL patients and 94% of TURP patients met the erectile function criterion. However, ejaculatory function at two years was preserved in 100% of PUL patients compared to 34% of the TURP patients. Incontinence was more likely in the TURP arm at two weeks and three months of follow-up, but did not significantly differ between the groups at 12 or 24 months of follow-up. The rates of serious adverse events and reintervention between the two groups at 12 months were reported in a previous study (Sonksen et al., 2015). Overall, Clavien-Dindo grade 1 adverse events occurred in 68% of PUL patients and 74% of TURP patients (p = 0.6); Clavien-Dindo grade 2 or 3 adverse events occurred in 16%

and 22% of patients respectively. Reintervention within one year occurred in three patients in the PUL arm (7%) and five patients in the TURP arm (14%) (p = 0.5).

CEbP researchers noted that the study was limited by the differential drop-out of patients randomized to the TURP arm. Five of the authors disclosed conflicts of interest with NeoTract, the maker of the PUL system.

Evidence Summary

There is moderate-quality evidence that PUL results in improvements in quality of life and prostate symptom scores and that those improvements persist at up to five years of follow-up. In a single small trial that directly compared PUL to TURP, symptom scores at two years were slightly better for TURP, and quality of life outcomes were similar in both groups. PUL did not appear to result in significant changes in sexual function or continence, and reduced the likelihood of ejaculatory dysfunction when compared to TURP. Adverse events (including pelvic pain, hematuria, dysuria, and transient urinary retention) were commonly reported, but generally limited to the first three months after the procedure and were similar to the rates observed with TURP. Reintervention rates at one year were numerically lower for PUL compared to TURP, but the differences were not statistically significant.

Policy Landscape

Payer Coverage Policies

Medicaid

No Washington Medicaid coverage policy was found for PUL.

Medicare

Three Local Coverage Determinations (LCDs), covering 18 states, were found for PUL: L36109, L36601, and L36775. The manufacturer's website for UroLift® states that all Medicare carriers provide benefits for PUL when medically necessary (NeoTract, 2017).

L36109 provides coverage for an initial implant and up to five additional implants, although implants in excess of six may be reconsidered on appeal. L36775 provides coverage for the PUL procedure once in a lifetime per beneficiary with a maximum of six implants. L36601 provides coverage for the surgical intervention with up to a total of six implants, although implants in excess of six may be reconsidered on an exception basis with a formal redetermination.

L36601 and L36775 provide coverage for PUL to treat BPH when all these conditions are met:

- Beneficiary is at least 50 years old with well-documented voiding symptoms consistent with prostatic hypertrophy
- AUA symptom index (AUASI) score ≥ 13
- Peak urine flow rate (Qmax) ≤ 12 cc/sec on a voided volume that is greater than 125 cc
- The beneficiary has had an adequate trial of, but is refractory to or intolerant of, usual BPH medication
- Prostate volume ≤ 80 cc without an obstructive median lobe
- There are no signs, symptoms, or diagnostic evidence of an active urinary infection and no history of bacterial prostatitis in the past three months
- The beneficiary is a poor candidate for other surgical interventions for BPH due to underlying disease (e.g., cardiac disease, pulmonary disease, etc.), or at high risk of bleeding, or the

beneficiary has opted for PUL based on likelihood of preserving erectile function, or there is another documented clinical reason for opting for PUL.

L36109 provides coverage for PUL for the treatment of symptomatic benign prostatic hyperplasia in men who are at least 50 years old when all these criteria are met:

- Moderate to severe BPH, defined as an AUA symptom score above 7 including signs of obstruction, such as increased voiding symptoms or decreased peak urinary flow rate (i.e., individual has a peak urine flow rate (Qmax) < 15 cc/sec on a voided volume that is greater than 125 cc
- Refractory to or intolerant of usual BPH medication
- Enlarged lateral lobes without an obstructive median lobe
- Prostatic volume ≤ 80 cc
- No active urinary infection
- Normal renal function

Private Payers

Coverage policies were searched for Aetna, Cigna, Moda, and Regence. No coverage policy on PUL was found for Moda.

The Aetna policy on BPH treatments (last reviewed 7/17/2017) provides coverage for PUL. The Cigna policy (effective 10/15/2017) states that PUL is considered medically necessary for the treatment of symptomatic BPH when all these criteria are met:

- Age 50 or above
- Estimated prostate volume < 80 cc
- No obstructive median lobe of the prostate identified on cystoscopy
- Failure, contraindication, or intolerance to at least three months of conventional medical therapy for BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

The Regence Clinical Position Statement on PUL (last reviewed 6/22/2017) states that PUL may be considered as an alternative to current surgical procedures for men aged 50 years and older with lower urinary tract symptoms of benign prostatic hyperplasia, who have a prostate of less than 100 ml without an obstructing middle lobe.

Recommendations from Others

Two guidelines were found that include recommendations on the use of PUL. The 2016 guidelines from the European Association of Urology conclude that PUL leads to objective and subjective short- and mid-term improvements in symptoms. However, according to the guideline authors, high-quality studies are needed to compare the efficacy, safety, and durability between PUL and other established invasive treatments (Gratzke et al., 2015).

A 2016 medical technology guidance from the National Institute for Health and Care Excellence (NICE) concludes that using PUL to treat symptoms of BPH is supported by the evidence if it is used in a day surgery unit. The NICE guidelines recommend that PUL be considered for use in men with lower urinary tract symptoms of BPH who are aged 50 years and older and who have a prostate of less than 100 cm^3. Cost modeling studies showed that PUL is cost saving compared with TURP (Ray et al., 2016).

Quality Measures

No quality measures were identified when searching the National Quality Measures Clearinghouse for prostatic urethral lift or BPH.

References

Evidence Sources

Gratzke, C., Barber, N., Speakman, M. J., Berges, R., Wetterauer, U., Greene, D., . . . Sonksen, J. (2017). Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. *BJU International, 119*(5), 767-775. doi: 10.1111/bju.13714

Perera, M., Roberts, M. J., Doi, S. A., & Bolton, D. (2015). Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: A systematic review and meta-analysis. *European Urology, 67*(4), 704-713. doi: 10.1016/j.eururo.2014.10.031

Roehrborn, C. G., Barkin, J., Gange, S. N., Shore, N. D., Giddens, J. L., Bolton, D. M., . . . Rukstalis, D. B. (2017). Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. *Canadian Journal of Urology, 24*(3), 8802-8813

Sonksen, J., Barber, N. J., Speakman, M. J., Berges, R., Wetterauer, U., Greene, D., . . . Gratzke, C. (2015). Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. *European Urology, 68*(4), 643-652. doi: 10.1016/j.eururo.2015.04.024

Other Citations

Gratzke, C., Bachmann, A., Descazeaud, A., Drake, M. J., Madersbacher, S., Mamoulakis, C., . . . Gravas, S. (2015). EAU Guidelines on the assessment of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. *European Urology, 67*(6), 1099-1109. doi: 10.1016/j.eururo.2014.12.038

Magistro, G., Chapple, C. R., Elhilali, M., Gilling, P., McVary, K. T., Roehrborn, C. G., . . . Gratzke, C. (2017). Emerging minimally invasive treatment options for male lower urinary tract symptoms. *European Urology, 72*(6), 986-997. doi: 10.1016/j.eururo.2017.07.005

NeoTract. (2017). *UroLift*. Retrieved from https://urolift.com/

Ray, A., Morgan, H., Wilkes, A., Carter, K., & Carolan-Rees, G. (2016). The Urolift System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: A NICE medical technology guidance. *Applied Health Economics and Health Policy, 14*(5), 515-526. doi: 10.1007/s40258-015-0218-x

Roehrborn, C. G. (2005). Benign prostatic hyperplasia: An overview. *Reviews in Urology, 7* Suppl 9, S3-s14.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (CEbP). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

CEbP is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of CEbP. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Appendix A. GRADE-Informed Framework Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical

sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Quality of life							
6	Mix of observational studies and 1 RCT	Moderate	Not serious	Not serious	Not serious	Large effect size	Moderate ●●●○
Need for reoperation							
6	Mix of observational studies and 1 RCT	Moderate	Not serious	Not serious	Serious		Low ●●○○
Procedural complications							
1	RCT	Moderate	Not estimable	Not serious	Serious		Very low ●○○○
Long-term harms							
1	RCT	Moderate	Not estimable	Not serious	Serious		Very low ●○○○
Change in prostate symptom scores							
6	Mix of observational studies and 1 RCT	Moderate	Not serious	Not serious	Not serious	Large effect size	Moderate ●●●○

Appendix C. Methods

Scope Statement

Populations

Men with benign prostatic hypertrophy (BPH) and lower urinary tract symptoms (LUTS)

Population scoping notes: None

Interventions

Prostatic urethral lift (PUL) procedure

Intervention exclusions: None

Comparators

Medical management (alpha blockers, 5-alpha reductase inhibitors), transurethral resection of the prostate (TURP), bipolar TURP, photoselective vaporization of the prostate (PVP), holmium laser enucleation of the prostate (HoLEP), transurethral incision of the prostate (TUIP), transurethral needle ablation of the prostate (TUNA), transurethral microwave thermotherapy (TUMT), bipolar transurethral electrovaporization of the prostate (TUVP), thulium laser vaporization/resection of the prostate

Outcomes

Critical: Quality of life

Important: Need for reoperation, procedural complications, long-term harms (e.g., urinary incontinence, erectile dysfunction), symptom improvement (e.g., International Prostate Symptom Score [IPSS], American Urological Association Symptom Index [AUASI] scores)

Considered but not selected for the GRADE table: Flow rate, post-void residual, post-procedural catheterization time, urinary retention

Key Questions

KQ1: What is the comparative effectiveness of PUL for men with lower urinary tract symptoms from BPH?

a. Does comparative effectiveness vary by baseline symptom severity?
b. Does the age of the patient or duration of symptoms affect the comparative effectiveness?

KQ2: What are the comparative harms of PUL for men with lower urinary tract symptoms from BPH?

Contextual Questions

CQ1: In what settings (outpatient, ambulatory surgical center, inpatient) and with what types of anesthesia or analgesia can PUL be safely performed?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2012.

The core sources searched included:

- Agency for Healthcare Research and Quality (AHRQ)
- Blue Cross/Blue Shield Center for Clinical Effectiveness
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Online Library)
- Institute for Clinical and Economic Review (ICER)
- Medicaid Evidence-based Decisions Project (MED)
- National Institute for Health and Care Excellence (NICE)
- Tufts Cost-effectiveness Analysis Registry
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search term prostatic urethral lift or Urolift. The search was limited to publications in English published since 2012. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the 2015 systematic review by Perera and colleagues.

Searches for clinical practice guidelines were limited to those published since 2012. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

- Australian Government National Health and Medical Research Council (NHMRC)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Centers for Disease Control and Prevention (CDC) – Community Preventive Services
- National Guidelines Clearinghouse
- National Institute for Health and Care Excellence (NICE)
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)
- Veterans Administration/Department of Defense (VA/DOD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
HCPCS Codes	
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

Note: Inclusion on this list does not guarantee coverage.