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Prostatic Urethral Lift

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Coverage

Use of prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia **may be considered medically necessary** when **ALL** of the following criteria are met:

- Individual has persistent or progressive lower urinary tract symptoms despite medical therapy (e.g., α_1-adrenergic antagonists maximally titrated, 5α-reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months, or is unable to tolerate medical therapy; AND
- Prostate gland volume is ≤80 mL; AND
- Individual does not have active urinary tract infection or recent prostatitis (within past year).

Use of PUL in all other situations **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to increased urinary frequency, an urgency to urinate, a hesitancy to urinate, nocturia, and a weak stream when urinating. The prostatic urethral lift (PUL) procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

Background

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia is a common disorder among older individuals that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection. Benign prostatic hyperplasia prevalence increases with age and is present in more than 80% of individuals ages 70 to 79 years. (1)

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. (2) Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤7), moderate (8-19), or severe (20-35). (1) The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score." (3)

Evaluation and management of BPH include assessment for other causes of lower urinary tract dysfunction (e.g., prostate cancer), symptom severity, and the degree that symptoms are bothersome to determine the therapeutic approach.

For patients with moderate-to-severe symptoms (e.g., an AUASI score of ≥8), bothersome symptoms, or both, a discussion about medical therapy is reasonable. Benign prostatic hyperplasia should generally be treated medically first. Available medical therapies for BPH-related lower urinary tract dysfunction include α-adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin), 5α-reductase inhibitors (e.g., finasteride, dutasteride), combination α-adrenergic blockers and 5α-reductase inhibitors, anti-muscarinic agents (e.g., darifenacin, solifenacin, oxybutynin), and phosphodiesterase-5 inhibitors (e.g., tadalafil). (1) In a meta-analysis of both indirect comparisons from placebo-controlled studies (including 6,333 patients) and direct comparative studies (including 507 patients), Djavan et al. (1999) found that the IPSS improved by 30% to 40% and the Qmax score (mean peak urinary flow rate) improved by 16% to 25% in individuals assigned to α-adrenergic blockers. (4) Combination therapy using an α-adrenergic blocker and 5α-reductase inhibitor has been shown to be more effective for improving IPSS than either treatment alone, with median scores improving by more than 40% over 1 year and by more than 45% over 4 years.

Patients who do not have sufficient response to medical therapy, or who are experiencing significant side effects with medical therapy, may be referred for surgical or ablative therapies. Various surgical and ablative procedures are used to treat BPH. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH procedures. (5) In the perioperative period, TURP is associated with risks of any operative procedure (e.g., anesthesia risks, blood loss). Although short-term mortality risks are generally low, a large prospective study with 10,654 patients by Reich et al. (2008) reported the following short-term complications: "failure to void (5.8%), surgical revision (5.6%), significant urinary tract infection (3.6%), bleeding requiring transfusions (2.9%), and transurethral resection syndrome (1.4%)." (6) Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with an increased risk of sexual dysfunction and incontinence.

Several minimally invasive prostate ablation procedures are available, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate. The minimally invasive procedures were individually compared with TURP at the time they were developed, which provided a general benchmark for evaluating those procedures. The American Urological Association (AUA) recommends surgical intervention for patients who have "renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with lower urinary tract symptoms (LUTS) attributed to BPH refractory to and/or unwilling to use other therapies." (7)

Regulatory Status

One implantable transprostatic tissue retractor system has been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2013, the NeoTract UroLift® System UL400 (NeoTract) was cleared (after receiving clearance through the FDA's de novo classification process in March 2013; K130651/DEN130023). In 2016, the FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to BPH in individuals ages 50 years and older. In 2017, the FDA expanded the indication for the UL400 and UL500 to include *lateral and median* lobe hyperplasia in men 45 years or older. An additional clearance in 2019 (K193269) modified an existing contraindication for use from men with a prostate volume of >80 cc to men with a prostate volume of >100 cc. FDA product code: PEW.

Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition.

Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Prostatic Urethral Lift

Clinical Context and Therapy Purpose

The purpose of prostatic urethral lift (PUL) in individuals who have lower urinary tract symptoms due to benign prostatic hyperplasia (BPH) is to provide a treatment option that is an alternative to or an improvement on existing therapies such as medical management or transurethral resection of the prostate (TURP).

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are experiencing lower urinary tract symptoms without a history suggesting non-BPH causes of the symptoms and who do not have a sufficient response to medical therapy or are experiencing significant side effects with medical therapy.

Interventions

The therapy being considered is PUL. The PUL procedure involves the placement of 1 or more implants in lobes of the prostate using a transurethral delivery device. The implant device is designed to retract the prostate to allow expansion of the prostatic urethra. The implants are retained in the prostate to maintain an expanded urethral lumen. One device, the NeoTract UroLift System, has been cleared for marketing by the FDA (see Regulatory Status section). The device has 2 main components: the delivery device and the implant. Each delivery device comes preloaded with a UroLift implant.

Comparators

The following practices are currently being used to treat BPH: TURP is generally considered the reference standard for comparisons of BPH procedures. Several minimally invasive prostate

ablation procedures have also been developed, including transurethral microwave thermotherapy, transurethral needle ablation of the prostate, urethromicroablation phototherapy, and photoselective vaporization of the prostate.

Outcomes
A number of health status measures are used to evaluate symptoms relevant to BPH and adverse events of treatment for BPH, including urinary symptoms, urinary dysfunction measured by urinary flow rate (Qmax), ejaculatory dysfunction, overall sexual health, and overall quality of life. Qmax is measured by uroflowmetry; low rates are associated with more voiding dysfunction and rates <10 mL/sec are considered obstructed.

Outcomes data demonstrating durability to at least 2 years is preferred.

Some validated patient-reported scales are shown in Table 1.

Of note, the prostate volume does not have a direct correlation with the severity of urinary symptoms. (8)

Table 1. Patient-Reported Health Outcome Measures Relevant to Benign Prostatic Hyperplasia

Measure	Outcome Evaluated	Description	Clinically Meaningful Difference (If Known)
Male Sexual Health Questionnaire for Ejaculatory Dysfunction (9)	Ejaculatory function and quality of life	Patient-administered, 4-item scale. Symptoms rated as absent [15] to severe [0]. QOL assessed as no problem [0] to extremely bothered [5].	NR
Sexual Health Inventory for Men (10)	Erectile function	Patient-administered, 5-item scale. Erectile dysfunction rated as severe [1-7], moderate [8-11], mild to moderate [12-16], or mild [17-21]. Fewest symptoms present for patients with scores 22-25.	5-point change (11)
American Urological Association Symptom Index (AUASI); International Prostate Symptom Score (IPSS) (1, 3, 12)	Severity of lower urinary tract symptoms	• Patient-administered, 7-item scale. Symptoms rated as mild [0-7], moderate [8-19], or severe [20-35]	• Minimum of 3-point change (1, 12) • Minimum of 30% change (13)

		• IPSS asks an additional question, rating QOL as delighted [0] to terrible [6]	
Benign Prostatic Hyperplasia Impact Index (2)	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale. Symptoms rated as absent [0] to severe [13].	Minimum of 0.4-point change (12)

NR: not reported; QOL: quality of life.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Initial Prostatic Urethral Lift Procedure

Several systematic reviews on PUL have been published. They include a similar set of trials and noncomparative studies. Perera et al. (2015) reported on the results of a systematic review and meta-analysis (14) of studies reporting outcomes after the PUL procedure, which included 7 prospective cohort studies, (15-21) a crossover study, (15) and the LIFT RCT. (22)

Shore (2015) (23) performed a systematic review of UroLift studies, which included the LIFT RCT (22); Roehrborn et al. (2015) (24); McVary et al. (2014) (25), a crossover study (15), and 4 prospective cohort studies (Garrido Abad et al. [2013] [26]; Chin et al. [2012] [18]; Woo et al. [2012] [19]; McNicholas et al. [2013] [17]).

Jones et al. (2016) performed a systematic review of UroLift studies with at least 12 months of follow-up. (27) Seven studies were identified, which included 4 noncomparative studies: Woo et al. (2011) (20), Chin et al. (2012) (18), McNicholas et al. (2013) (17), Bozkurt et al. (2016) (28), a crossover study (15), and 2 RCTs (LIFT [22] and BPH6 [11]).

The National Institute for Health and Care Excellence (NICE) (2016) published a technical guidance on prostatic lift procedures. (29) The Institute performed a literature search and data synthesis to support development of the guidance. Studies selected were the same studies included in Perera et al. (2015) (14), except for the exclusion of Hoffman et al. (2012) (21) in the analysis.

Tanneru et al. (2020) published a systematic review and meta-analysis of studies with at least 24 months of follow-up. (30) Five studies were included; 3 noncomparative studies (Chin et al. [2012] [18], Rukstalis [2016] [31], Sievert et al. [2020] [32]) and 2 RCTs (LIFT and BPH6).

Perera et al. (2015), Shore (2015), Jones et al. (2016), and Tanneru et al. (2020) analyzed data from the PUL arms of the studies only and the NICE review was published before the BPH6 RCT. Therefore, these systematic reviews will not be discussed further.

Jung et al. (2019) published a Cochrane systematic review of PUL parallel-group RCTs published up to January 2019. (33) The 2 included RCTs (N=297) were the LIFT and BPH6 trials described in detail in the following section. (22, 34) The two RCTs included different comparators and results were not combined meta-analytically. The authors used the GRADE approach to rate the certainty of the evidence. The conclusions were as follows:

- PUL appears less effective than TURP in improving urological symptoms, both in the short-term and long-term (low-certainty evidence);
- PUL may result in a similar QOL compared to TURP (low-certainty evidence);
- PUL may result in similar erectile function compared to TURP (moderate-certainty evidence);
- PUL may result in better ejaculatory function compared to TURP (moderate-certainty evidence);
- Rates of major adverse events are unclear (very low-certainty evidence);
- Rates of retreatment are unclear (very low-certainty evidence).

In 2022, Franco et al. published a Cochrane network meta-analysis assessing the comparative effectiveness of minimally invasive treatments for lower urinary tract symptoms in men with BPH. (35) Twenty-seven trials representing 3017 men were included through February 2021. Compared to TURP, PUL and prostatic arterial embolization (PAE) were found to result in little to no difference in urological symptoms, while convective water vapor thermal therapy (e.g., Rezum), transurethral microwave thermotherapy (TUMT), and temporary implantable nitinol devices (TIND) may result in worse urological outcomes. While minimally invasive treatments were found to result in little to no difference in quality of life compared to TURP, they were found to result in a large reduction in major adverse events. The overall certainty of the evidence according to GRADE criteria was low to very low across these outcomes. The authors were uncertain of the effects of PUL on erectile function (mean difference of International Index of Erectile Function, 3.00; 95% confidence interval [CI], -5.45 to 11.44), ejaculatory dysfunction (RR 0.05; 95% CI, 0.00 to 1.06), and retreatment rates (RR 2.39; CI, 0.5 to 11.1) compared to TURP. Retreatment was defined as the number of participants requiring a follow-up procedure for lower urinary tract symptoms with another minimally invasive treatment or TURP, excluding follow-up procedures to treat complications, which were evaluated as major adverse events.

<u>Randomized Controlled Trials</u>

Two RCTs of PUL have been performed. Key trial characteristics and study results are shown below in Tables 2, 3, 6, and 7. Additionally, a brief description of each trial is provided in the following sections.

Table 2. Prostatic Urethral Lift Randomized Controlled Trial Characteristics

Study: Trial	Countries	Sites	Dates	Inclusion Criteria		Interventions, n	
					Baseline Prostate Volume, cm^3	Active	Comparator
Sonksen et al. (2015) (11); BPH6	Denmark, Germany, U.K.	10	Feb 2012-Oct 2013	Age ≥50 y, IPSS >12, prostate volume ≤60 cm^3, without median lobe obstruction	16-59	PUL=46	TURP=45
Roehrborn et al. (2013) (22); LIFT	U.S., Canada, Australia	19	Feb-Dec 2011	Age ≥50 y, IPSS ≥13, prostate volume 30-80 cm^3, washed out of BPH medications, without median lobe obstruction	30-77	PUL=140	Sham=66

BPH: benign prostatic hypertrophy; IPSS: International Prostate Symptom Score; PUL: prostatic urethral lift; TURP: transurethral resection of the prostate; y: year(s).

BPH6 Study

Sonksen et al. (2015) reported on the results of a multicenter RCT comparing the PUL procedure with TURP among individuals ages 50 and older with lower urinary tract symptoms, secondary to benign prostatic obstruction. (11) Eligible patients had an International Prostate Symptom Score (IPSS) above 12, a Qmax of 15 mL/s or less for a 125-mL voided volume, a postvoid residual volume less than 350 mL, and prostate volume of 60 cm^3 or less on ultrasound. Patients were excluded if there was a median lobe obstruction in the prostate or signs of active infection. The trial used a novel composite endpoint, referred to as the BPH6, which included the following criteria:

- Lower urinary tract symptom relief: Reduction in IPSS by ≥30% within 12 months, relative to baseline.

- Recovery experience: Self-assessed by patients as ≥70% within 1 month, using a visual analog scale.
- Erectile function: Reduction in Sexual Health Inventory for Men (SHIM) score by ≤6 points within 12 months, relative to baseline.
- Ejaculatory function: Emission of semen as assessed by question 3 in the Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD).
- Continence preservation: Incontinence Severity Index ≤4 points at all follow-up visits.
- Safety: No treatment-related adverse events exceeding grade 1 on the Clavien-Dindo classification system at time of procedure or any follow-up.

Patients were considered treatment responders if they met all 6 composite criteria. While this composite endpoint has not been previously validated, core components of the composite score have been independently validated in a clinical setting. The trial used a noninferiority design with a margin of 10% for the primary endpoint, BPH6. Study investigators modified 2 of the original endpoint definitions in the study's analysis, including changing the sexual function element assessment from a single time point (12 months) to assess sustained effects during 12 months of follow-up, and lowering the threshold of quality of recovery on a visual analog scale from 80 to 70.

Table 3. Summary of Evidence From the BPH6 Study

Outcomes	**3 Months**		**12 Months**		**24 Months**	
	PUL	**TURP**	**PUL**	**TURP**	**PUL**	**TURP**
Mean change in IPSS						
n	42	34	40	32	37	32
Mean (SD)	-11.7 (8.5)	-11.8 (9.5)	-10.9 (7.9)	-15.4 (6.8)	-9.2 (9.2)	-15.3 (7.5)
p	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Comparison (p)	0.978		0.013		0.004	
Change in IPSS QOL						
n	43	34	40	32	37	32
Mean (SD)	-2.6 (1.7)	-2.4 (2.0)	-2.8 (1.8)	-3.1 (1.6)	-2.5 (1.8)	-3.3 (1.6)
p	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Comparison (p)	0.55		0.436		0.066	
Change in Qmax						
n	33	25	32	29	27	27
Mean (SD)	4.2 (5.0)	12.7 (9.8)	4.0 (4.8)	13.7 (10.4)	5.0 (5.5)	15.8 (16.5)
p	<0.001	0.003	<0.001	0.003	<0.001	0.002
Comparison (p)	<0.001		<0.001		0.002	
Change in SHIM score						
n	38	27	32	27	29	28

Mean (SD)	-0.7 (5.2)	-1.0 (5.2)	-0.1 (4.7)	-0.9 (4.3)	-0.2 (4.3)	-1.8 (4.90)
p	0.386	0.328	0.940	0.29	0.832	0.067
Comparison (p)	0.861		0.486		0.201	
Change in MSHQ- EjD function score						
n	38	27	32	27	29	27
Mean (SD)	-0.7 (2.1)	-3.0 (4.1)	1.3 (3.3)	-3.7 (4.1)	0.3 (3.4)	-4.0 (4.6)
p	0.251	<0.001		<0.001	0.666	<0.001
Comparison (p)	<0.001		<0.001		<0.001	
Change in MSHQ- EjD bother score						
n	38	28	32	27	29	27
Mean (SD)	-0.7 (2.1)	0.2 (1.5)	0.5 (2.2)	0.0 (1.5)	-0.1 (2.2)	-0.3 (1.9)
p	0.062	0.470	0.214	0.896	0.734	0.415
Comparison (p)	0.069		0.359		0.771	
Composite score	NR	NR	Response: 52%	Response: 20%	NR	NR
Comparison (95% CI); *p*	NR		Difference: 32% (10% to 51%); 0.005		NR	
Clavien-Dindo adverse events						
Grade 1, n (%)	NR	NR	30 (68)	26 (74)	NR	NR
Adverse events			60	79		
Grade 2, n (%)	NR	NR	3 (7)	4 (11)	NR	NR
Adverse events			3	5		
Grade 3, n (%)	NR	NR	4 (9)	5 (14)	NR	NR
Adverse events			4	5		

Adapted from Gratzke et al. (2017). (34)

BPH: benign prostatic hypertrophy; CI: confidence interval; IPSS: International Prostate Symptom Score; n: number; MSHQ-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NR: not reported; PUL: prostatic urethral lift; Qmax: mean peak urinary flow rate; QOL: quality of life; SD: standard deviation; SHIM: Sexual Health Inventory for Men; TURP: transurethral resection of the prostate.

Ninety-one patients were randomized to TURP (n=45) or PUL (n=46). Ten patients in the TURP group and 1 patient in the PUL group declined treatment, leaving an analysis group of 80 subjects. The analysis was per-protocol, including 35 in the TURP group and 44 in the PUL group (87% of those randomized; 1 patient was excluded for violating the active urinary retention exclusion criterion). Groups were similar at baseline, except for the MSHQ-EjD function score. For procedure recovery, 82% of the PUL group achieved the recovery endpoint by 1 month compared with 53% of the TURP group (p=.008). For the study's primary outcome, the proportion of participants who met the original BPH6 primary endpoint was 34.9% for the PUL group, and 8.6% for the TURP group (noninferiority p<.001; superiority p=.006). The modified BPH6 primary endpoint was met by 52.3% of the PUL group and 20.0% of the TURP group

(noninferiority p<.001; superiority p=.005). Both groups demonstrated improvements over IPSS, IPSS quality of life score, BPH-II score, and Qmax over time, as described in Table 3. There were 60 grade 1 adverse events in 30 (68%) PUL patients and 79 adverse events in 26 (74%) TURP patients. The number of patients experiencing grade 2 and 3 adverse events was similar between groups. Intention-to-treat analyses were not reported.

Gratzke et al. (2017) reported on 2-year results from BPH6. (34) Two additional patients were excluded from the analysis: 1 TURP patient who discontinued participation; and 1 PUL patient who had a protocol violation. Composite scores for the 2 groups were not reported. Both groups continued to show significant improvements in IPSS score, IPSS quality of life, BPH-II score, and Qmax during the 2 year follow-up, as described in Table 3. Six (14%) PUL patients and 2 (6%) TURP patients had secondary treatment (PUL, intradetrusor botulinum toxin, laser or TURP procedure), showing moderate durability over 2 years.

Tables 4 and 5 display notable limitations identified in each study.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
BPH6	3: Unclear history of BPH treatments			4: Primary outcome was not validated	
LIFT	3: Unclear history of BPH treatments		2: Men were washed out of medication		

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
BPH: benign prostatic hypertrophy.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest; 5. Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
BPH6		1. Blinding not feasible		6. Only per-protocol analysis presented		

LIFT				1, 2, 5. High losses and/or exclusions in extended follow-up, only LOCF sensitivity analyses provided		3, 4. CI not reported for treatment effects

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
CI: confidence interval; LOCF: last observation carried forward.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

LIFT Study

Roehrborn et al. (2013) reported on results of the pivotal LIFT study, an RCT comparing PUL with sham control among 206 individuals ages 50 years and older with lower urinary tract symptoms secondary to BPH. (22) Eligible patients had an American Urological Association Symptom Index (AUASI) score of 13 or greater, Qmax of 12 mL/s or less for a 125-mL voided volume, and a prostate volume between 30 and 80 mL. Patients were excluded if there was median lobe obstruction in the prostate, postvoid obstruction of more than 250 mL, or signs of active infection. Patients underwent a washout of BPH medications before enrollment; the washout period was 2 weeks for α-blockers and 3 months for 5α-reductase inhibitors. Patients were randomized to PUL (n=140) or sham control (n=66) and evaluated at 3 months postprocedure for the trial's primary efficacy endpoint. After that, all patients were unblinded, and sham control patients were permitted to undergo the PUL procedure. Fifty-three control subjects eventually underwent a PUL procedure. The analysis was intention-to-treat. The study met its primary efficacy endpoint, which was that the reduction in AUASI score at 3 months postprocedure had to be at least 25% greater after the PUL than the reduction in AUASI score seen with sham (p=.003). The AUASI score decreased from 24.4 at baseline to 18.5 at 3-month follow-up for sham control patients and from 22.2 at baseline to 11.2 at 3-month follow-up for PUL patients (Table 6). The 3-month change in Qmax was 4.28 mL/s for PUL patients and 1.98 mL/s for sham control patients (p=.005). Compared with sham control patients, PUL patients had greater improvements in quality of life scores and BPH-II score (Table 7). Nine serious adverse events in 7 patients were reported in the PUL group, and 1 serious adverse event was

reported in the sham group during the first 3 months of follow-up. Limitations in the trial design are summarized in Tables 4 and 5.

McVary et al. (2014) reported on sexual function outcomes in a subset of patients from the LIFT study. (25) At baseline, 53 (38%) PUL subjects and 23 (53%) sham control subjects were sexually inactive or had severe erectile dysfunction and were censored from the primary sexual function analysis. Scores on the SHIM, MSHQ-EjD function scale, and the MSHQ-EjD bother scale did not differ significantly between groups.

Table 6. Summary of LIFT Initial Trial Results

Study	Change in IPSS	Change in IPSS QOL	Change in Qmax	Change in MSHQ-EjD Function	Change in MSHQ-EjD Bother	Any Adverse Events, n (%)	Serious Adverse Events, n (%)
LIFT							
N at 3 months	206	206	182	144	177	206	206
PUL	-11.1 (7.7)	-2.2 (1.8)	4.3 (5.2)	2.2 (2.5)	-0.8 (1.5)	122 (87%)	7 (5%)
Adverse events						268	9
Sham	-5.9 (7.7)	-1.0 (1.5)	2.0 (4.9)	1.7 (2.6)	-0.7 (1.6)	43 (52%)	1 (1.5%)
Adverse events						53	1
TE (p)	NR (0.003)	NR (<0.001)	NR (0.005)	NR (0.283)	NR (0.60)	NR	NR

Adapted from Roehrborn et al. (2013). (22)
Values are mean (standard deviation) unless otherwise indicated.
IPSS: International Prostate Symptom Score; MSHQ-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; N: number; NR: not reported; PUL: prostatic urethral lift; Qmax: mean peak urinary flow rate; QOL: quality of life; TE: treatment effect.

Table 7. Summary of Evidence for LIFT Study, Including Participants in the PUL Group

Outcomes	3 Months	1 Year	2 Years	3 Years	5 Years
N	140	129	118	109	87
Death/LTFU	0	2	7	2	18
Protocol deviations	3	0	0	1	0
Retreatment	0	6	4	6	4
Change in IPSS					
n	136	123	103	93	72
Change	-11.14 (7.72)	-10.61 (7.51)	-9.13 (7.62)	-8.83 (7.41)	-35.9%

95% CI	-12.45 to -9.83	-11.95 to -9.27	-10.62 to -7.64	-10.35 to -7.30	-44.4% to -27.3%
p	<0.001	<0.001	<0.001	<0.001	<0.001
Change in IPSS QOL					
n	136	123	103	93	72
Change	-2.22 (1.78)	-2.31 (1.60)	2.19 (1.72)	-2.25 (1.72)	-50.3
95% CI	-2.52 to -1.92	-2.59 to -2.02	-2.53 to -1.86	-2.60 to -1.89	-58.4% to -42.2%
p	<0.001	<0.001	<0.001	<0.001	<0.001
Change in Qmax					
n	122	102	86	69	52
Change	4.29 (5.16)	4.03 (4.96)	4.21 (5.09)	3.47 (5.00)	44.3%
95% CI	3.36 to 5.21	3.06 to 5.00	3.12 to 5.30	2.27 to 4.67	29.4% to 59.1%
p	<0.001	<0.001	<0.001	<0.001	<0.001
Change in SHIM score					
n	91	87	72	66	NR
Change	1.27 (4.65)	0.70 (5.12)	1.06 (4.78)	0.53 (4.41)	NR
95% CI	0.31 to 2.24	-0.39 to 1.79	-0.07 to 2.18	-0.55 to 1.62	NR
p	0.005	0.299	0.046	0.338	NR
Change in MSHQ-EjD function score					
n	91	87	72	66	49
Change	2.31 (2.58)	1.56 (2.68)	1.08 (2.51)	0.56 (2.48)	9.3%
95% CI	1.77 to 2.85	0.99 to 2.13	0.49 to 1.67	-0.05 to 1.17	-3.8% to 22.5%
p	<0.001	<0.001	<0.001	0.013	0.096
Change in MSHQ-EjD bother score					
n	91	87	72	66	49
Change	-1.07 (1.44)	-0.76 (-1.55)	0.63 (1.51)	-0.59 (1.52)	-6.3%
95% CI	-1.37 to -0.77	-1.09 to -0.43	-0.98 to -0.27	-0.96 to -0.22	-31.5% to 18.8%
p	<0.001	<0.001	<0.001	<0.001	0.019

Adapted from Roehrborn et al. (2016) (36) for data from 3 months to 3 years and Roehrborn et al. (2017) (37) for data for 5 years.
While not specifically indicated, change values likely represent means and standard deviations.
CI: 95% confidence interval; IPSS: International Prostate Symptom Score; LTFU: lost to follow-up; MSHQ-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; N/n: number; NR: not reported; PUL: prostatic urethral lift; Qmax: mean peak urinary flow rate; QOL: quality of life; SHIM: Sexual Health Inventory for Men.

Cantwell et al. (2014) reported on 12-month outcomes for 53 subjects in the LIFT sham control group who underwent PUL after unblinding at 3 months postprocedure. (15) Crossover (unblinded) patients had a change in IPSS from 23.4 to 12.3 at 3 months postprocedure

compared with the change in IPSS from 25.2 to 20.2 at 3 months after the sham procedure. Subjects had greater improvements in BPH-II score in the crossover period (-3.3) than in the sham period (-1.9; p=.024) but did not report significant differences in improvement in Qmax. Change in sexual function scores did not differ significantly after the sham procedure compared with after the active procedure.

Rukstalis et al. (2016) reported on 24-month outcomes for 42 of the 53 participants in the LIFT sham group who underwent PUL after unblinding. (31) During the 24 months, 4 patients were known to have had TURP, and 1 patient required additional PUL implants. The change in IPSS from baseline to 24 months was -9.6 (-35%; 95% CI, not reported; p<.001) and there were significant score improvements in Qmax, BPH-II scores, and quality of life. There were no significant changes compared with baseline for SHIM scores; however, MSHQ-EjD scores improved by 41% (p<.001).

Roehrborn et al. (2015) reported on 3-year results from patients randomized to PUL in the LIFT study. (24) After exclusion of 11 subjects who were lost to follow-up, 36 subjects with missing data, protocol deviations, medication treatment for BPH, or other prostate procedures, and 15 subjects who underwent surgical retreatment for lower urinary tract symptoms (6 with repeat PUL procedures, 9 with TURP or laser vaporization), the 3-year effectiveness analysis included 93 (66%) of the original 140 subjects. For subjects with follow-up data, change in IPSS was -8.83 (95% CI, -10.35 to -7.30; p<.001). Significant improvements were also reported for the quality of life score, BPH-II score, and Qmax. Sexual function was unchanged. Implants were removed from 10 participants. No analyses were performed to assess how sensitive the results were to changes in the assumptions about the considerable amount of missing data.

Roehrborn et al. (2016) reported on 4-year results from patients randomized to PUL in the LIFT study. (36) Of the 140 originally randomized patients, 32 were lost by the 4-year follow-up visit (6 losses were deaths). Of the remaining 108 patients for whom data were available, an additional 29 patients were excluded from analysis for BPH retreatment or protocol deviations. For the 79 (56%) of the 140 subjects included in the analysis, change in IPSS score was -8.8 (precision not given) or -41% (95% CI, -49% to -33%; p<.001). Significant improvements (vs baseline) were also reported for scores relating to the quality of life, BPH-II, and Qmax. Authors reported that 14% "of the 140 originally enrolled" participants had surgical retreatment at some point during the 4 years; however, the 4-year follow-up included 79 patients, so the denominator for the 14% is not clear, and estimated retreatment rates are likely underestimated since individuals lost to follow-up could also have received retreatment. Attributes of patients who received retreatment were not analyzed. SHIM scores did not differ statistically from baseline.

Roehrborn et al. (2017) reported on 5-year results from patients randomized to PUL in the LIFT study. (37) The authors reported 2 analyses. The first was called a per-protocol analysis, which censored patients who had additional BPH procedures, started a BPH medication, or had a protocol deviation. A second analysis was called an intention-to-treat analysis, which used the last observation carried forward to impute values that were censored in the per-protocol

analysis. While there were 104 participants with 5-year data, only 72 patients (approximately 50% of those randomized) were included in the per-protocol analysis after exclusion for protocol violations, additional BPH procedures, or treatment with BPH medication. In the intention-to-treat analysis, change in IPSS was -7.85 at 5 years (-35%; 95% CI, -41% to -29%; p<.001). In the per-protocol analysis, change in IPSS was -7.56 at 5 years (-35.9%; 95% CI, -44% to -27%). Significant improvements, compared with baseline, continued to be reported for scores associated with quality of life, Qmax, and BPH-II. Of the limited number of patients that remained in the analysis, 13.6% had surgical reintervention by 5 years.

Subsection Summary: Randomized Controlled Trials

The BPH6 study demonstrated that PUL is noninferior to TURP when assessed by a composite score, which reflects concurrent improvements in validated scales of symptoms, safety, and sexual function. These findings are reflected in the analysis of the individual aspects of the composite score. Prostatic urethral lift demonstrates measurable improvements in urinary symptoms to 2 years and is superior to TURP in preserving ejaculatory function. These findings were confirmed in the LIFT study, which compared PUL with a sham treatment. Prior to crossover at 3 months, patients were found to have greater improvement in urinary symptoms relative to patients receiving sham treatment and preserved sexual function. After 3 months, 80% of patients who had received a sham treatment chose to have the PUL procedure. Patients treated with PUL had improvement of urinary symptoms with preservation of sexual function, consistent with the BPH6 study. These findings were preserved in a subset of patients over 3 to 5 years; a high number of patients were either excluded or lost to follow-up during this time. The BPH6 and LIFT RCTs excluded men with median lobe obstruction.

Nonrandomized Studies

The approved indications for PUL have expanded since the original approval to include men with median lobe obstruction and those with prostate volume between 80cc and 100cc. Neither of these expansions have supporting RCTs.

Median Lobe Obstruction

Several noncomparative studies were published including men without median lobe obstruction. These studies were previously enumerated in the description of the systematic reviews. Since RCTs with long-term follow-up exist for this population, these noncomparative studies will not be discussed in further detail.

Rukstalis et al. (2019) reported results of the prospective MedLift study, the study used to support the expansion of the FDA clearance for PUL to include obstructive median lobes. (38) MedLift was a single-arm study enrolling 45 men with eligibility criteria identical to LIFT except requiring obstructive median lobes. Results in the MedLift cohort were compared to the LIFT historical cohort. Characteristics are shown in Table 8 and results are shown in Table 9. One patient required surgical retreatment and no implants were removed over the 12 months of follow-up.

Eure et al. (2023) published results from a real-world retrospective database analysis (N=2078) of consecutive PUL patients filtered to match MedLift criteria with results stratified by obstructive median lobe (n=180) or lateral lobe (n=1271) morphology. (39) Characteristics are shown in Table 8 and results through 12 months are shown in Table 9. Additionally, no statistically significant differences were noted with comparison of the MedLift cohort versus TURP control subjects in the BPH6 RCT at 12 months for IPSS, QoL, and post-void residual outcomes (not shown below).

Table 8. Summary of Characteristics of Key Nonrandomized Studies

Study	Country	Sites	Participants	Treatment Delivery	Follow-Up
Rukstalis (2019) (38)	US	9	Men ages 50+ with IPSS >13, Qmax ≤12 mL/s, 30 to 80 cc intraurethral prostatic volume and. OML[a] (n=45)	UroLift PUL procedure with median lobe deployment	12 months
Eure (2023) (39)	US	22	Patients not in retention at baseline, IPSS ≥8 and no prior BPH treatment filtered to match MedLift (n=180 with OML; n=1279 with LL)	UroLift PUL procedure with median lobe or lateral lobe deployment	12 months

BPH: benign prostatic hyperplasia; IPSS: International Prostate Symptom Score; LL: lateral lobe; n: number; PUL: prostatic urethral lift; Qmax: mean peak urinary flow rate; US: United States.
[a] OML (obstructive median lobe) was defined as excessive posterior tissue that precludes a normal lateral lobe procedure.

Table 9. Summary Results of Key Nonrandomized Studies

Study	IPSS	IPSS QOL	Qmax	SHIM
Rukstalis (2019) (38)	At 12 months	At 12 months	At 12 months	At 12 months
OML (n)	44	44	37	38
Change from baseline, mean (SD); p-value	-13.5 (7.7); p<0.001	-3.0 (1.5); p<0.001	6.4 (7.4); p<0.001	1.2 (4.3); p=0.04
Eure (2023) (39)	At 12 months OML: 30 LL: 241	At 12 months OML: 25 LL: 155	At 12 months OML: 1 LL: 42	At 12 months
OML: Change from baseline, mean (SD)	-11.6 (9.2)	-2.1 (2.0)	7.1 (NR)	NR
LL: Change from baseline, mean (SD)	-8.5 (7.5)	-1.6 (1.6)	3.1 (6.7)	NR

Change versus MedLift for OML and LL; p-value	.56; <.01	.06; <.01	.99; .1	NR

IPSS: International Prostate Symptom Score; LL: lateral lobe; n: number; NR: not reported; OML: obstructive median lobe; Qmax: mean peak urinary flow rate; QOL: quality of life; SHIM: Sexual Health Inventory for Men; SD: standard deviation.

Tables 10 and 11 display notable limitations identified in each study.

Table 10. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Rukstalis (2019) (38)	3. Unclear history of BPH treatments		2: No concurrent comparator	3: Reporting of adverse events was qualitative; rates not reported	1, 2: Only 12 months of follow-up reported
Eure (2023) (39)			2: No concurrent comparator		1, 2: Only 12 months of follow-up reported

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
BPH: benign prostatic hypertrophy.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest; 5. Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Rukstalis (2019) (38)	1,2: Not randomized	1,2: No blinding		1. >15% missing data for Qmax and SHIM		3: CIs not reported

Eure (2023) (39)	1,2: Not randomized; retrospective design	1,2. No blinding		1. >80% missing data for IPSS; incomplete baseline data across other outcomes		3. CIs not reported

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
CI: confidence interval; IPSS: International Prostate Symptom Score; Qmax: mean peak urinary flow; SHIM: Sexual Health Inventory for Men.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Prostate Volume Greater Than 80 mL

Sievert et al. (2019) reported results of a noncomparative study that included 5 men with prostate volume greater than 80 mL. (32) Results were not presented stratified by prostate volume.

Shah et al. (2018) reported a retrospective review of 74 patients at a single institution that had undergone PUL between 2014 and 2015. (40) Twenty-three of the patients had prostates larger than 80 g (median, 112 g; range, 81 to 254 g); 5 of the men with larger prostates had obstructive median lobe. Overall, median follow-up time between the date of PUL procedure and the last reported symptom rating during follow-up was 144 days; follow-up was not reported separately for the men with a larger prostate volume. In the men with larger prostate volume, the median pre-operative AUA symptom score was 12. Twenty of the 23 men had post-operative AUA symptom scores with a median score of 3 (median improvement = 9; p<.001). Three (13%) of the men with a larger prostate volume had a repeat outlet procedure.

Eure et al. (2019) (41) included 38 men with a prostate volume >80 mL. Although the authors reported that "no significant differences in symptom response emerged based on prostate volume," results were not presented stratified by volume.

Bozkurt et al. (2016) (28), Woo et al. (2012) (19), and Chin et al. (2012) (18) included men with a prostate volume greater than 80 mL, but had a mean volume in the 40 to 60 mL range. It is unclear how many patients had a volume greater than 80 mL.

Given the limited amount of published data on outcomes for men with a prostate volume greater than 80 mL and limited follow-up, the risks and benefits cannot be evaluated.

Subsection Summary: Noncomparative Studies

One single-arm study (N=45) including men with obstructive median lobes has been conducted and was used to support the FDA expansion of the PUL indication. Symptom scores and quality of life appeared to improve by statistically and clinically significant amounts and were similar in magnitude to improvements reported in the original LIFT study. Rates of adverse events were not reported. Design and conduct limitations preclude interpretation.

Noncomparative studies have included a small number of men with a larger prostate volume, but have generally not reported results stratified by volume. One study presented data for 20 men with less than 6 months of follow-up.

Summary of Evidence

For individuals who have lower urinary tract obstruction symptoms due to benign prostatic hyperplasia (BPH) who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a prostatic urethral lift (PUL), the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One RCT, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate (TURP) and reported that the PUL procedure was noninferior for the study's composite endpoint, which required concurrent fulfillment of 6 independently validated measures of symptoms, safety, and sexual health. While TURP was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to TURP in preserving ejaculatory function. These findings were corroborated by another RCT (the LIFT study), which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported these findings were preserved in a subset of patients over 3 to 5 years; however, a high number of patients were either excluded or lost to follow-up during this time. The BPH6 and LIFT RCTs included men with a prostate volume up to 80 cm^3 and excluded men with median lobe obstruction. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Urological Association

In 2018, the American Urological Association published guidelines on the surgical management of LUTS attributed to BPH; the 2018 guidelines were amended 2021. (7) The guidelines made the following recommendations and statements regarding PUL.

- "PUL may be offered as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume 30-80cc and verified absence of an obstructive middle lobe."
    - "Moderate Recommendation; Evidence Level: Grade C" indicating "Benefits > Risks/Burdens (or vice versa); Net benefit (or net harm) appears moderate. Applies to most patients in most circumstances but better evidence is likely to change confidence."
- "PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function."
    - "Conditional Recommendation; Evidence Level: Grade C indicating "Risks/Burdens unclear; Alternative strategies may be equally reasonable. Better evidence likely to change confidence."
- "Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally invasive treatments for LUTS secondary to BPH."
- "Surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS/BPH refractory to or unwilling to use other therapies."

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence published guidance on urethral lift implants to treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). (42) The guidance stated:

"Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure."

In 2021, the National Institute for Health and Care Excellence published updated guidance on the use of UroLift for treating LUTS of BPH. (43) The guidance stated: "the UroLift system relieves lower urinary tract symptoms, avoids risk to sexual function, and improves quality of life" and "the UroLift system should be considered as an alternative to transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). It can be done as a day-case or outpatient procedure for people aged 50 and older with a prostate volume between 30 and 80 mL."

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in Table 12.

Table 12. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06037356	Prostatic Urethral Lift Versus Transurethral Resection of Prostate in Benign Prostatic Hyperplasia Patients With Urinary Retention	100	May 2032 (recruiting)
NCT04987892[a]	Investigating Medication vs. Prostatic Urethral Lift: Assessment and Comparison of Therapies for Benign Prostatic Hyperplasia	250	Oct 2025 (recruiting)
NCT05784558[a]	RELIEF Study: Real-world Evaluation of LUTS Interventions and Patient Experience During Follow-up	2500	Dec 2030 (not yet recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	52441, 52442
HCPCS Codes	C9739, C9740

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
10/15/2025	Reviewed. No changes.
02/01/2025	Document updated with literature review. Coverage unchanged. No new references added.
02/01/2024	Document updated with literature review. Coverage unchanged. Added references 7, 36, and 40.
10/15/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. Coverage unchanged. The following references were added/updated: 7, 31, 33, 39-40 and 42.
04/01/2021	Document updated with literature review. The following changes were made to Coverage: 1) Modified conditional coverage criteria. Added references 32, 37, and 40. Title changed from: Prostatic Urethral Lift (PUL) for the Treatment of Benign Prostatic Hyperplasia (BPH).
09/01/2018	Document updated with literature review. The following changes were made to Coverage: 1) Decreased age criterion from 50 to 45 years or older, 2) Removed "Peak flow rate (Qmax) ≤ 12mL/second" criterion, 3) Removed "No obstructive median lobe" criterion, 4) Added examples of conservative management options, and 5) Added experimental, investigational and/or unproven statement for all other situations not meeting criteria. The following references were added: 4-6, 8, 11, 27, 32-35, 37; several references removed.
10/15/2017	Reviewed. No changes.
12/01/2016	Document updated with literature review. Coverage unchanged.
12/01/2015	Document updated with literature review. The coverage position was changed to consider the UroLift system medically necessary for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) when meeting all the following criteria: men age 50 and older, prostate sizes no greater than 80 grams per ultrasound, international prostate symptom score ≥ 13, peak flow rate (Qmax) ≤ 12mLs, no obstructive median lobe, no active urinary tract infection, when conservative management options have been unsuccessful, or are not appropriate, and when surgical intervention is indicated.
06/15/2015	New medical document. Prostatic urethral lift (PUL) for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH)), including but not limited to the use of the UroLift® System (transprostatic permanent delivery device and implant), is considered experimental, investigational and/or unproven.