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Title: Prostatic Urethral Lift

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Populations	Interventions	Comparators	Outcomes
Individuals: • With lower urinary tract obstruction symptoms due to benign prostatic hyperplasia who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy	Interventions of interest are: • Prostatic urethral lift	Comparators of interest are: • Transurethral resection of the prostate • Minimally invasive prostate resection or ablation • Continued medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With lower urinary tract obstruction symptoms due to benign prostatic hyperplasia who have had a prior prostatic urethral lift	Interventions of interest are: • Repeat prostatic urethral lift	Comparators of interest are: • Transurethral resection of the prostate • Minimally invasive prostate resection or ablation • Continued medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related morbidity

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.

OBJECTIVE

The objective of this evidence review is to determine whether prostatic urethral lift improves the net health outcome in individuals with benign prostatic hyperplasia.

BACKGROUND

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) 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.

POLICY

A. 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:

1. The individual has persistent or progressive lower urinary tract symptoms despite medical therapy (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**

2. Prostate gland volume is ≤80 mL; **AND**

3. Individual does not have urinary retention related to conditions other than benign prostatic hyperplasia, urinary tract infection, or recent prostatitis (within past year); **AND**

4. Individual has had appropriate testing to exclude diagnosis of prostate cancer; **AND**

5. Individual does not have a nickel, titanium, or stainless steel allergy.

B. Use of prostatic urethral lift in other situations, including repeat procedures, is considered **experimental / investigational**.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through June 14, 2024.

Evidence reviews 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 review.

Populations

The relevant population of interest is men 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; International Prostate Symptom Score [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) IPSS asks an additional question, rating QOL as delighted (0) to terrible (6)	• Minimum of 3-point change [12,1,] • Minimum of 30% change[13,]
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,]

IPSS: International Prostate Symptom Score; QOL: quality of life; NR: Not reported.

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 long-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.

REVIEW OF EVIDENCE

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. The overlap of studies is shown in Appendix Table 3. 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,[15,16,17,18,19,20,21,] 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 (2016) published a technical guidance on prostatic lift procedures.[29,] The Institute performed a literature search and data synthesis to support the 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 National Institute for Health and Care Excellence 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 Jan 2019.[33,]. The 2 included RCTs (N=297) were the LIFT and BPH6 trials described in detail in the following section.[22,34,] The 2 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 quality of life 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% CI, -5.45 to 11.44), ejaculatory dysfunction (RR 0.05; 95% CI, 0.00 to 1.06), and retreatment rates (RR 2.39; 95% confidence interval [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.

Randomized Controlled Trials

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	30-77	PUL=140	Sham=66

Study; Trial	Countries	Sites	Dates	Inclusion Criteria		Interventions, n	
				median lobe obstruction			

BPH: benign prostatic hyperplasia; IPSS: International Prostate Symptom Score; PUL: prostatic urethral lift; TURP: transurethral resection of the prostate.

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

Outcomes	**3 Months**		**12 Months**		**24 Months**	
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	<.001	<.001	<.001	<.001	<.001	<.001
Comparison (p)	.978		.013		.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	<.001	<.001	<.001	<.001	<.001	<.001
Comparison (p)	.55		.436		.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	<.001	.003	<.001	.003	<.001	.002
Comparison (p)	<.001		<.001		.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	.386	.328	.940	.29	.832	.067
Comparison (p)	.861		.486		.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	.251	<.001		<.001	.666	<.001

Outcomes	**3 Months**		**12 Months**		**24 Months**	
Comparison (p)	<.001		<.001		<.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	.062	.470	.214	.896	.734	.415
Comparison (p)	.069		.359		.771	
Composite score	NR	NR	Response: 52%	Response: 20%	NR	NR
Comparison (95% CI); p	NR		Difference: 32%(10% to 51%);.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 hyperplasia; CI: confidence interval; IPSS: International Prostate Symptom Score; 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]	Duration of 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 review; this is not a comprehensive gaps assessment.
BPH: benign prostatic hyperplasia.
[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 (e.g., proposed as an adjunct but not tested as such); 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. Incomplete 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 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

Comparative Data

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 (.003)	NR (<.001)	NR (.005)	NR (.283)	NR (.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; 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 Prostatic Urethral Lift 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					

Outcomes	3 Months	1 Year	2 Years	3 Years	5 Years
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	<.001	<.001	<.001	<.001	<.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	<.001	<.001	<.001	<.001	<.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	<.001	<.001	<.001	<.001	<.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	.005	.299	.046	.338	NR
Change in MSHQ-EjD function score					
n	91	87	72	66	49

Outcomes	3 Months	1 Year	2 Years	3 Years	5 Years
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	<.001	<.001	<.001	.013	.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	<.001	<.001	<.001	<.001	.019

Adapted from Roehrborn et al (2015)[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: confidence interval; IPSS: International Prostate Symptom Score; LTFU: lost to follow-up; 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; SHIM: Sexual Health Inventory for Men.

Follow-Up of Sham-Assigned Crossover Participants

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).

Follow-Up of Prostatic Urethral Lift-Assigned Participants

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.

Section 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 and are shown in Appendix Table 3. 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; OML: obstructive median lobe; PUL: prostatic urethral lift; Qmax: mean peak urinary flow rate.
[a]OML 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 m	At 12 m	At 12 m	At 12 m
OML (n)	44	44	37	38
Change from baseline, mean (SD); p-value	-13.5 (7.7); p<.001	-3.0 (1.5); p<.001	6.4 (7.4); p<.001	1.2 (4.3); p=.04
Eure (2023)[39,]	At 12 m OML: 30 LL: 241	At 12 m OML: 25 LL: 155	At 12 m OML: 1 LL: 42	At 12 m
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; 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. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of 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 m of follow-up reported
Eure (2023)[39,]			2: No concurrent comparator		1, 2: Only 12 m of follow-up reported

The study limitations stated in this table are those notable in the current 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 (e.g., proposed as an adjunct but not tested as such); 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. Incomplete 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 review; this is not a comprehensive gaps assessment.
CI: confidence interval; IPSS: International Prostate Symptom Score; Qmax: mean peak urinary flow rate; 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.

Section 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.

REPEAT PROSTATIC URETHRAL LIFT

Clinical Context and Therapy Purpose
The purpose of repeat PUL in individuals with lower urinary tract obstruction symptoms due to BPH who have had a prior PUL is to provide a treatment option that is an alternative to or an improvement on existing therapies such as medical management or TURP.

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

Populations
The relevant population of interest is men who are experiencing lower urinary tract symptoms without a history of an alternative non-BPH etiology and who have undergone a prior PUL.

Interventions
The therapy being considered is repeat 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 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,]

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 long-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.

Review of Evidence
Clinical data are limited regarding PUL reintervention/retreatment and investigators continue to emphasize the need for consensus definitions of these outcomes in future studies.[42,43,] The majority of data concerning lower urinary tract symptoms/BPH define retreatment, reintervention, or treatment failure in an individualized manner with considerable variation across trials. Studies assessing the need for additional surgical procedures (for implant misplacement, malfunction, encrustation, infection, or lack of continued efficacy), failure to remove or wean off BPH medications, or the initiation of new BPH medications after the initial intervention have all been evaluated.[44,] There is no consensus definition of retreatment/reintervention in this setting or regulatory guidance. Additionally, data on factors that may identify patients at high risk for retreatment/reintervention such as measures of patient symptoms, prostate specific antigen levels, or prostatic volumes are often absent in the reporting.

Retreatment rates in the long-term follow-up of the LIFT study were reviewed in the Follow-Up of PUL-Assigned Participants section of this evidence review. Of the limited number of patients that remained in the analysis, 13.6% had a surgical reintervention by 5 years.[37,]

Systematic Reviews
Shin et al (2024) conducted a systematic review and network meta-analysis of reintervention rates for surgical interventions, including PUL, Aquablation, Rezum, PAE, temporary implantable nitinol device (iTIND), and TURP for BPH.[45,] Thirty-two studies were included, including 10 RCTs and 22 prospective observational studies (N=2400). At 12 months, the cumulative reintervention rate for PAE was 8.0% (95% CI: 3.2% to 12.9%; p=.001), for PUL was 4.8% (95% CI: 1.8% to 7.8%; p=.002), and for Rezum was 1.5% (95% CI: 0.5% to 2.5%; p=.004). At 24 months, the cumulative reintervention rate was higher for PUL at 16.5% (95% CI: 9.9% to 23.1%; p<.001) compared to TURP at 2.9% (95% CI: 0.06% to 5.2%; p=.013). Of note, the results have been reported as percentages and cross-referenced with the cumulative reintervention rates presented in the respective figure in this reference. The results in the text of this reference appeared to incorrectly report the proportions as percentages.

Miller et al (2020) reported results of a systematic review and meta-analysis on the surgical reintervention rate of PUL utilizing a life table method.[46,] Randomized or nonrandomized controlled studies and prospective and retrospective observational studies published through January 2020 were eligible for inclusion. Eleven studies (9 observational, 2 RCTs) were included with a total of 2016 patients. There were 153 surgical reinterventions performed (TURP, 51.0%; repeat PUL, 32.7%, device explant, 19.6%). Per the authors, the annual rate of surgical reintervention was 6.0% per year (95% CI, 3.0% to 8.9%): 4.3% per year in studies with ≤1 year mean follow-up, 10.7% per year in studies with >1 year to 3 years mean follow-up, and 5.8% per year in 1 study with >3 years mean follow-up. No information was provided on the success of the reinterventions.

Observational Studies

Gaffney et al (2021) performed a retrospective healthcare system database analysis of inpatient and ambulatory endoscopic procedures for BPH, identifying 175,150 men treated between 2000 and 2018.[47,] More than half were treated with TURP, compared to 27% with prostate photovaporization and 10% with PUL. Readmission rates at 30 days were 2.2% for TURP, 2.1% for prostate photovaporization, and 1.2% for PUL (odds ratio [OR], 0.58; p <.01). Ninety-day readmission rates were 5.7% for TURP, 6.0% for prostate photovaporization, and 2.9% for PUL (OR, 0.55; p<.01). However, patients treated with PUL were almost twice as likely to be retreated at 2-year follow-up compared to those receiving TURP (OR, 1.78; p<.01). Retreatment rates at 2-years were 5.2% for PUL, 3.2% for prostate photovaporization, and 2.9% for TURP.

Page et al (2021) identified a retrospective observational cohort (N=2942 UroLift procedures from 2942 patients) and reported on care setting real world experience outcomes of PUL procedures conducted in hospitals across England.[48,] During follow-up, 206 patients required retreatment with 57 patients (4.2%) requiring further UroLift intervention and 158 patients (5.4%) requiring endoscopic interventions. Subsequent UroLift treatment at 1 and 2 years was 1.5% (95% CI, 1.0 to 2.0) and 3% (95% CI, 2.1 to 3.8), respectively, while subsequent endoscopic treatment (no UroLift) was 3.9% (95% CI, 3.0 to 4.7) and 9.5% (95% CI, 7.9 to 10.1). The overall retreatment rate at 1 and 2 years was 5.2% (95% CI, 4.2 to 6.1) and 11.9% (95% CI, 10.1 to 13.6), respectively.

Eure et al (2019) completed a retrospective chart review and analysis of 1413 patients who underwent a PUL procedure in North America and Australia.[41,] In this study, 72 patients underwent either a PUL retreatment (n=39) or an alternative surgical intervention (17 laser procedures; 16 TURPs), 11 of which included implant removal.

Section Summary: Repeat Prostatic Urethral Lift

Clinical data on repeat PUL are limited and there is no consensus on definitions of clinically meaningful types of retreatment or reintervention and their associated outcomes. The 5 year surgical reintervention rate in the LIFT study was reported as 13.6% while a meta-analysis calculated a surgical reintervention rate following PUL at 6% per year. One analysis of clinical care setting real world experience reported the overall retreatment rate at 1 and 2 years to be 5.2% (95% CI, 4.2 to 6.1) and 11.9% (95% CI, 10.1 to 13.6), respectively, following an initial PUL. A retrospective healthcare system database analysis of endoscopic procedures for BPH (N=175,150) found that patients treated with PUL were almost twice as likely to be retreated at 2-year follow-up compared to those receiving TURP (OR, 1.78; p<.01).

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017

Clinical input was sought to help determine whether the use of PUL for individuals with lower urinary tract obstruction symptoms due to BPH who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, while this policy was under review in 2017, clinical input on the use of a prostatic urethral lift for 3 indications were received from 4 respondents, including 2 physician-level responses identified through a specialty society and 2 physician-level responses identified through an academic medical center. Input consistently supported that the use of PUL for individuals with moderate-to-severe lower urinary tract obstruction symptoms due to BPH provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice. See Appendices 1 and 2 for details of the clinical input.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association

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

- "PUL may be offered as an option for patients with LUTS [lower urinary tract symptoms] /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/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).[49,] 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.[50,] 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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 12.

Table 12. Summary of Key Trials

NCT No.	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

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
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)
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

REVISIONS	
01-01-2017	Policy added to the bcbsks.com web site on 12-01-2016 with an effective date of 01-01-2017.
01-30-2018	Updated Description section.
	In Policy section: ▪ Removed previous policy language, "The prostatic urethral lift procedure is considered experimental / investigational for all indications." ▪ Added new policy language, " A. 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: 1. Patient is not an appropriate candidate for a surgical procedure using general anesthesia, such as transurethral resection of the prostate, due to a chronic medical condition including but not limited to cardiopulmonary disease or chronic anticoagulation therapy; AND 2. Patient has persistent or progressive lower urinary tract symptoms or is unable to tolerate medical therapy (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; AND 3. Prostate gland volume is ≤80 mL; AND 4. Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND 5. Patient does not have urinary retention, urinary tract infection, or recent prostatitis (within past year); AND 6. Patient does not have prostate-specific antigen level ≥3 ng/mL, or has had appropriate testing to exclude diagnosis of prostate cancer; AND 7. Patient does not have a contact dermatitis nickel allergy. B. The prostatic urethral lift procedure in other situations is considered experimental / investigational."
	Updated Rationale section.
	In Coding section: ▪ Added ICD-10 code.

REVISIONS	
	Updated References section.
11-07-2018	Updated Description section.
	In Policy section: ▪ In Item A, added "in individuals 45 years of age or older" to read, "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 in individuals 45 years of age or older when ALL of the following criteria are met:" ▪ Removed previous Item A 1, "Patient is not an appropriate candidate for a surgical procedure using general anesthesia, such as transurethral resection of the prostate, due to a chronic medical condition including but not limited to cardiopulmonary disease or chronic anticoagulation therapy; AND" ▪ In new Item A 1 (previously Item A 2), added "despite" to read, "The patient has persistent or progressive lower urinary tract symptoms despite medical therapy (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" ▪ Removed previous Item A 4, "Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND" ▪ In new Item A 3 (previously Item A 5), removed "urinary retention" to read, "Patient does not have urinary tract infection or recent prostatitis (within past year)"
	Updated Rationale section.
	Updated References section.
02-24-2021	Updated Description section
	Updated Rationale section
	Updated References section
	Added Appendix 1 and 2
10-08-2021	Updated Description section
	In Policy section: ~~B. The prostatic urethral lift procedure in other situations is considered experimental / investigational.~~ B <u>Use of prostatic urethral lift in other situations, including repeat procedures, is considered</u> experimental / investigational.
	Updated Rationale section.
	Updated References section.
09-27-2022	Updated Description Section
	Updated Policy Section ▪ Section A5 Added: "titanium, or stainless steel" now reads "Individual does not have a nickel, titanium, or stainless steel allergy."
	Updated Rationale Section
	Updated References Section
	Removed Appendix Section
10-02-2023	Updated Description Section
	Updated Policy Section ▪ Section A Removed: "in individuals 45 years of age or older" ▪ Section A3 Added: "urinary retention related to conditions other than benign prostatic hyperplasia," ▪ Section A4 Removed: "does not have prostate-specific antigen level ≥3 ng/mL, or"
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes

REVISIONS	
	Updated References Section
10-08-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section

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