BlueCross BlueShield of Alabama

Name of Policy:
Prostatic Urethral Lift

Policy #: 610
Category: Surgery
Latest Review Date: September 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Benign Prostatic Hyperplasia

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

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

Management of BPH

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

Medical Therapy

A discussion about medical therapy is generally indicated for patients with moderate-to-severe symptoms (e.g., AUASI score, ≥8), bothersome symptoms, or both. 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). A 1999 meta-analysis of both indirect comparisons from placebo-controlled studies (including 6333 patients) and direct comparative studies (including 507 patients) 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. 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.

Surgical and Ablative Therapies

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 or ablative procedures are used to treat BPH. Transurethral resection of the prostate (TURP) is generally considered the reference standard for comparisons of BPH treatments. 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, one large prospective study with 10,654 patients 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%)." Incidental carcinoma of the prostate was diagnosed by histologic examination in 9.8% of patients. In the longer term, TURP is associated with risk of sexual dysfunction and incontinence.

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. The minimally invasive procedures were individually compared with transurethral resection of the prostate at the time they were developed, which provided a general benchmark for evaluating those procedures.

Policy:

Effective for dates of service on or after March 1, 2018:

Use of a **prostatic urethral lift** in individuals **≥45 years of age with moderate to severe lower urinary tract obstruction due to benign prostatic hyperplasia meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **when ALL of the following criteria are met**:

- ~~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**~~
- The patient has persistent or progressive lower urinary tract symptoms despite medical therapy (α1-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**
- Prostate anatomy demonstrates normal bladder neck; **AND**
- The patient does not have urinary retention, urinary tract infection, urinary incontinence, current gross hematuria, **or** recent prostatitis (within past year); **AND**
- ~~Patient does not have prostate-specific antigen level ≥3 ng/mL, or has had appropriate testing to exclude diagnosis of prostate cancer~~

Use of a **prostatic urethral lift in all other situations does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

For dates of service prior to March 1, 2018:

The **prostatic urethral lift procedure does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for any indication and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's

contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was updated through October 9, 2017.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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 (PUL)

Clinical Context and Therapy Purpose

The purpose of prostatic urethral lift (PUL) in patients 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 question addressed in this evidence review is: Does PUL improve the net health outcome in individuals with BPH?

The following PICOTS were used to select literature to inform this review.

Patients

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 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 placement of one or more implants in the lateral 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 U.S. Food and Drug
Administration (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
Various surgical or ablative procedures are 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 dysfunction measured by urinary flow rate (Qmax), ejaculatory dysfunction, overall sexual health, and overall quality of life. Some validated patient-reported scales are shown in Table 1. Of note, prostate volume does not have a direct correlation with severity of urinary symptoms.

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 (MSHQ-EjD)	Ejaculatory function	Patient-administered, 4-item scale	
Sexual Health Inventory for Men (SHIM)	Erectile function	Patient-administered, 5-item scale; final score range, 1 (worst symptoms) to 25 (fewest symptoms)	
American Urological Association Symptom Index (AUASI)	Severity of lower urinary tract symptoms	Patient-administered, 7-item scale; final score range, 0 (no symptoms) to 35 (worst symptoms)	Minimum of 3-point change
Benign Prostatic Hyperplasia Impact Index (BPH-II)	Effect of urinary symptoms on health domains	Patient-administered, 4-item scale; final score range, 0 (best) to 13 (worst)	Minimum of 0.4-point change

QOL: quality of life

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

Setting
Medical management of BPH may occur in the primary or secondary care setting. Men needing surgical management are referred to urologists with experience in surgical procedures for treating BPH.

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
Several systematic reviews have been published. They include a similar set of trials and noncomparative studies.

In 2015, Perera et al reported results of a systematic review and meta-analysis of studies reporting outcomes after the PUL procedure, which included 7 prospective cohort studies, a crossover study (Cantwell et al), and the LIFT RCT (Reohrborn et al, McVary et al). The pooled standardized mean gain (SMG) estimates for prostate symptoms scores (International Prostate Symptom Score [IPSS], Benign Prostatic Hyperplasia Impact Index [BPH-II]) and sexual health scores used responses from 452 to 680 patients. SMG for prostatic symptoms scores ranged from -1.3 (95% confidence interval [CI], -1.4 to -1.2) to -1.6 (95% CI, -1.7 to -1.3), which translated into a clinically meaningful improvement. The SGM for sexual health scores ranged from 0.3 (95% CI, 0.2 to 0.4) to 0.4 (95% CI, 0.3 to 0.5), suggesting a small improvement.

Also in 2015, Shore performed a systematic review of UroLift studies, which included the LIFT RCT (Roehrborn et al [2013]; Roehrborn et al [2015]; McVary et al [2014]), a crossover study (Cantwell et al [2014]), and 4 prospective cohort studies (Garrido Abad et al [2013]; Chin et al [2012]; Woo et al [2012]; McNicholas et al [2013]). Only data that showed absolute change, supported by a 95% CI or standard deviation, was included in the weighted analysis. Reviewers reported that, from 0.5 to 1.5 months to 2 years, mean peak urinary flow rate (Qmax) increased from 3.3 to 4.15, IPSS improved from -4.5 to -9.2 relative to baseline, quality of life improved from -1.2 to -2.2 relative to baseline, and BPH-II scores improved from -0.1 to -3.8 relative to baseline. Changes in post-void residual volume were not statistically significant.

In 2016, Jones, et al performed a systematic review of UroLift studies with at least 12 months of follow-up. Seven studies were identified, which included 4 noncomparative studies (Woo et al, Chin et al, McNicholas et al, Bozkurt et al), 1 crossover study (Cantwell et al), and 2 RCTs (LIFT and BPH6). The review included data from 440 patients. Only the data from men in the UroLift arms of these RCTs were included. Results were combined to create summaries but the meta-analytic methods used to combine the data were not described and precision estimates were

not given. The authors reported that mean peak urinary flow rate (Qmax) increased from 8.4 mL/s to 11.8 mL/s, mean IPSS improved from 24.1 to 14, mean quality of life (QOL) improved from 4.5 to 2.3, and mean 5-item International Index of Erectile Function score improved from 17.7 to 18.2. The most frequent complications reported were dysuria, hematuria and pelvic pain.

The National Institute for Health and Care Excellence (NICE) published a technical guidance on prostatic lift procedures in 2016. The NICE External Assessment Centre (EAC) performed a literature search and data synthesis to support development of the guidance. Studies selected were the same studies included in Perera et al, except for the exclusion of Hoffman et al and the inclusion of Abad et al (2013) in the analysis. Comparators for the review were TURP and holmium laser enucleation of prostate (HoLEP). When the literature search was performed, there were no studies directly comparing PUL to either TURP or HoLEP. Therefore the NICE EAC extracted data from a TURP versus HoLEP systematic review to perform a "pragmatic indirect comparison" of these comparators to prostatic lift procedures. The conclusion of the review was that PUL provides significant improvement in IPSS, BPH-II, and QOL (estimates of effect similar to Perera et al) but with improvements that were smaller than those seen with TURP or HoLEP; however, the PUL procedure was associated with a slight improvement in erectile or ejaculatory function.

Randomized Controlled Trials

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

Table 2. PUL Randomized Controlled Trial Characteristics

						Interventions, n	
Author (Year), Study	**Countries**	**Sites**	**Dates**	**Inclusion Criteria**	**Baseline Prostate Volume, cm3**	**Active**	**Comparator**
Sonksen et al (2015); BPH6	Denmark, Germany, U.K.	10	Feb 2012-Oct 2013	Age ≥50 y, IPSS >12, prostate volume ≤60 cm^3	16-59	PUL (46)	TURP (45)
Roehrborn et al (2013); 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	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.

BPH6 Study

In 2015, Sonksen et al reported results of a multicenter RCT comparing the prostatic urethral lift procedure with TURP among men aged 50 and over with lower urinary tract symptoms secondary to benign prostatic obstruction. Eligible patients had an International Prostate Symptom Score (IPSS) above 12, a peak urinary flow rate (Qmax) of 15 mL/s or less for a 125-mL voided volume, a post-void residual volume less than 350 mL, and prostate volume of 60 cm^3 or less on ultrasound. Patients were excluded if there was median lobe obstruction in the prostate or signs of active infection. The study used a novel composite end point, 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 or procedure or any follow-up.

Patients were considered treatment responders if they met all six composite criteria. While this composite end point had not been previously validated, core components of the composite score have been independently validated in a clinical setting. The study used a non-inferiority design with a margin of 10% for the BPH6 primary end point. Study investigators modified two of the original end point 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 VAS from 80 to 70.

Table 3. Summary of Evidence From the BPH6 Study

Outcomes	3 Months, Mean (SD)		12 Months, Mean (SD)		24 Months, Mean (SD)	
	PUL	TURP	PUL	TURP	PUL	TURP
Mean change in IPSS	n=42 -11.7 (8.5) p<0.001	n=34 -11.8 (9.5) p<0.001	n=40 -10.9 (7.9) p<0.001	n=32 -15.4 (6.8) p<0.001	n=37 -9.2 (9.2) p<0.001	n=32 -15.3 (7.5) p<0.001
Comparison	0.978		p=0.013		p=0.004	
Change in IPSS QOL	n=43 -2.6 (1.7) p<0.001	n=34 -2.4 (2.0) p<0.001	n=40 -2.8 (1.8) p<0.001	n=32 -3.1 (1.6) p<0.001	n=37 -2.5 (1.80 p<0.001	n=32 -3.3 (1.6) p < 0.001
Comparison	p=0.55		p=0.436		p=0.066	
Change in Qmax	n=33 4.2 (5.0) p<0.001	n=25 12.7 (9.8) p=0.003	n=32 4.0 (4.8) p<0.001	n=29 13.7 (10.4) p=0.003	n=27 5.0 (5.5) p<0.001	n=27 15.8 (16.5) p=0.002
Comparison	p<0.001		p<0.001		p=0.002	
Change in SHIM score	n=38 -0.7 (5.2) p=0.386	n=27 -1.0 (5.2) p=0.328	n=32 -0.1 (4.7) p=0.940	n=27 -0.9 (4.3) p=0.29	n=29 -0.2 (4.3) p=0.832	n=28 -1.8 (4.90 p=0.067
Comparison	p=0.861		p=0.486		p=0.201	
Change in MSHQ-EjD function score	n=38 -0.7 (2.1) p=0.251	n=27 -3.0 (4.1) p<0.001	n=32 1.3 (3.3) p=0.03	n=27 -3.7 (4.1) p<0.001	n=29 0.3 (3.4) p=0.666	n=27 -4.0 (4.6) p<0.001
Comparison	p<0.001		p<0.001		p<0.001	
Change in MSHQ-EjD bother score	n=38 -0.7 (2.1) p=0.062	n=28 0.2 (1.5) p=0.470	n=32 0.5 (2.20 p=0.214	n=27 0.0 (1.5) p=0.896	n=29 -0.1 (2.2) p=0.734	n=27 -0.3 (1.9) p=0.415
Comparison	p=0.069		p=0.359		p=0.771	
Composite score	NR	NR	Response: 52%	Response: 20%	NR	NR

Outcomes	3 Months, Mean (SD)		12 Months, Mean (SD)		24 Months, Mean (SD)	
Comparison	NR		Difference: 32% (95% CI, 10% to 51%) p=0.005		NR	
Clavien-Dindo Adverse Events			**n (%)**	**n (%)**		
Grade 1	NR	NR	30 (68%) AE=60	26 (74%) AE=79	NR	NR
Grade 2	NR	NR	3 (7%) AE=3	4 (11%) AE=5	NR	NR
Grade 3	NR	NR	4 (9%) AE=4	5 (14%) AE=5	NR	NR

Adapted from Gratzke et al (2017).31
AE: adverse event; BPH: benign prostatic hypertrophy; 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 prostatic urethral lift (n=46). Ten patients in the TURP group and one patient in the prostatic urethral lift group declined treatment, leaving an analysis group of 80 subjects. Analysis was per-protocol, including 35 in the TURP group and 44 in the prostatic urethral group (87% of those randomized; one patient was excluded for violation of the active urinary retention exclusion criterion). Groups were similar at baseline, with the exception of MSHQ-EjD Function score. For procedure recovery, 82% of the prostatic urethral lift group achieved the recovery end point by one month compared with 53% of the TURP group (p=0.008). For the study's primary outcome, the proportion of participants who met the original BPH6 primary end point was 34.9% for the prostatic urethral lift group and 8.6% for the TURP group (non-inferiority p<0.001; superiority p=0.006). The modified BPH6 primary end point was met by 52.3% of the prostatic urethral lift group and 20.0% of the TURP group (non-inferiority p<0.001; superiority p=0.005). Both groups demonstrated improvements over IPSS, IPSS Quality of Life score, Benign Prostatic Hyperplasia Impact Index (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. Two additional patients were excluded from 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 in this study. 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.

Subsection Summary: BPH6 Study
In the BPH6 study, PUL was both noninferior (p<0.001) and superior (p=0.005) to TURP for the study's composite end point. This end point was calculated using the concurrent achievement of validated measures of symptoms and complications and is sufficient to describe patient health

outcomes. TURP was associated with greater improvements in urinary tract obstruction symptom outcomes and with greater declines in ejaculatory function compared with PUL.

LIFT Study

Comparative Data

In 2013, Roehrborn et al reported results of the pivotal LIFT study, an RCT comparing prostatic urethral lift with sham control among 206 men aged 50 and older with lower urinary tract symptoms secondary to BPH. Eligible patients had an American Urological Association Symptom Index (AUASI) 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, post-void obstruction of more than 250 mL, or signs of active infection. Patients underwent 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 prostatic urethral lift (n=140) or sham control (n=66) and evaluated at three months postprocedure for the study's primary efficacy end point. After that, all patients were unblinded and sham control patients were permitted to undergo the prostatic urethral lift procedure. Fifty-three control subjects eventually underwent a prostatic urethral lift procedure. Analysis was intention-to-treat. The study met its primary efficacy end point that the reduction in AUASI score at three months postprocedure was at least 25% greater after the prostatic urethral lift than that seen with sham (p=0.003). The AUASI score decreased from 24.4 at baseline to 18.5 at three month follow-up for sham control patients and from 22.2 at baseline to 11.2 at three month follow-up for prostatic urethral lift patients (See Table 4). The three month change in Qmax was 4.28 mL/s for prostatic urethral lift patients and 1.98 mL/s for sham control patients (p=0.005). Compared with sham control patients, prostatic urethral lift patients had greater increases in quality of life scores (note that specific quality of life scoring device was not specified) and BPH-II score (See Table 5). 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.

McVary et al (2014) reported on sexual function outcomes in a subset of patients from the LIFT study. At baseline, 53 (38%) prostatic urethral lift 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 and MSHQ-EjD Function scale and the MSHQ-EjD Bother scale did not differ significantly between groups.

Table 4. 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							
At 3 months	N=206	N=206	n=182	n=144	n=177	N=206	N=206
PUL	-11.1 (7.7)	-2.2 (1.8)	4.3 (5.2)	2.2 (2.5)	-0.8 (1.5)	122 (87%) AE=268	7 (5%) AE= 9
Sham	-5.9 (7.7)	-1.0 (1.5)	2.0 (4.9)	1.7 (2.6)	-0.7 (1.6)	43 (52%) AE=53	1 (1.5%) AE=1

Treatment effect	NR (p=0.003)	NR (p<0.001)	NR (p=0.005)	NR (p=0.283)	NR (p=0.60)	NR	NR

Values are mean (standard deviation) unless otherwise indicated.
AE: adverse event; 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.

Table 5. 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/loss to follow-up	0	2	7	2	18
Protocol deviations	3	0	0	1	0
Retreatment	0	6	4	6	4
Change in IPSS	n=136 Δ: -11.14 (7.72) (CI, -12.45 to -9.83) p<0.001	n=123 Δ: -10.61 (7.51) (CI, -11.95 to -9.27) p<0.001	n=103 Δ: -9.13 (7.62) (CI, -10.62 to -7.64) p<0.001	n=93 Δ: -8.83 (7.41) (CI, -10.35 to -7.30) p<0.001	n=72 %Δ: -35.9% (CI, -44.4% to -27.3%) p<0.0001
Change in IPSS QOL	n=136 Δ: -2.22 (1.78) (CI, -2.52 to -1.92) p<0.001	n=123 Δ: -2.31 (1.60) (CI, -2.59 to -2.02) p<0.001	n=103 Δ: 2.19 (1.72) (CI, -2.53 to -1.86) p<0.001	n=93 Δ: -2.25 (1.72) (CI, -2.60 to -1.89) p<0.001	n=72 %Δ: -50.3 (CI, -58.4% to -42.2%) p<0.0001
Change in Qmax	n=122 Δ: 4.29 (5.160 (CI, 3.36 to 5.21) p<0.001	n=102 Δ: 4.03 (4.96) (CI, 3.06 to 5.00) p<0.001	n=86 Δ: 4.21 (5.09) (CI, 3.12 to 5.30) p<0.001	n=69 Δ: 3.47 (5.00) (CI, 2.27 to 4.67) p<0.001	n=52 Δ: 44.3% (CI, 29.4% to 59.1%) p<0.001
Change in SHIM score	n=91 Δ: 1.27 (4.65) (CI, 0.31 to 2.24) p=0.005	n=87 Δ: 0.70 (5.12) (CI, -0.39 to 1.79) p=0.299	n=72 Δ: 1.06 (4.78) (CI, -0.07 to 2.18) p=0.046	n=66 Δ: 0.53 (4.41) (CI, -0.55 to 1.62) p=0.338	NR
Change in MSHQ-EjD function score	n=91 Δ: 2.31 (2.58) (CI, 1.77 to 2.85) p<0.001	n=87 Δ: 1.56 (2.68) (CI, 0.99 to 2.13) p<0.001	n=72 Δ: 1.08 (2.51) (CI, 0.49 to 1.67) p<0.001	n=66 Δ: 0.56 (2.48) (CI, -0.05 to 1.17) p=0.013	n=49 %Δ: 9.3% (CI, -3.8% to 22.5%) p=0.0962
Change in MSHQ-EjD bother score	n=91 Δ: -1.07 (1.44) (CI, -1.37 to -0.77) p<0.001	n=87 Δ: -0.76 (-1.55) (CI, -1.09 to -0.430 p<0.001	n=72 Δ: -0.63 (1.51) (CI, -0.98 to -0.27) p<0.001	n=66 Δ: -0.59 (1.52) (CI, -0.96 to -0.22) p<0.001	n=49 %Δ: -6.3% (CI, -31.5% to 18.8%) p=0.0195

Adapted from Roehrborn et al (2015) for data from 3 months to 3 years and Roehrborn et al (2017) for data for 5 years. While not specifically indicated, change values likely represent mean and standard deviation values.
Δ: change; BPH: Benign Prostatic Hypertrophy; CI: 95% 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; SHIM: Sexual Health Inventory for Men.

Follow-Up of Sham-Assigned Crossover Participants
In 2014, Cantwell et al reported on 12 month outcomes for the 53 subjects in the LIFT sham control group who underwent prostatic urethral lift after un-blinding at three months postprocedure. Crossover (unblinded) patients had a change in IPSS score from 23.4 to 12.3 at three months postprocedure compared with the change in IPSS score from 25.2 to 20.2 at three months after the sham procedure. Subjects had greater improvements in BPH-II score in the crossover period than in the sham period (-3.3 vs -1.9, p=0.024), but did not have significant differences in improvement in Qmax. Change in sexual function scores did not differ significantly after sham procedure compared with after 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. 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, NR; p<0.001) 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<0.001).

Follow-Up of PUL-Assigned Participants
In 2015, Roehrborn et al reported three year results from patients randomized to prostatic urethral lift in the LIFT study. After exclusion of 11 subjects who were lost to follow-up, 36 subjects who either had missing data, protocol deviations, medication treatment for BPH, or other prostate procedures, and 15 subjects who underwent surgical retreatment for lower urinary tract symptoms (six with repeat prostatic urethral lift procedures, nine with TURP or laser vaporization), the three year effectiveness analysis included 93 (66%) of the original 140 subjects. For subjects included in the follow-up data, change in IPSS score was -8.83 (95% CI, -10.35 to -7.30, p<0.001). Significant improvements were also reported for quality of life score, BPH-II score, and Qmax Sexual function was unchanged. Implants were removed from ten participants. No analyses were performed to assess how sensitive the results were to changes in the assumptions about the considerable amount of missing data.

In 2016, Roehrborn et al reported 4-year results from patients randomized to PUL in the LIFT study. 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% Cl, -49% to -33%; p<0.001). Significant improvements compared to baseline were also reported for QOL, BPH-II, and Qmax. Authors reported that fourteen percent of the 140 originally enrolled participants had surgical retreatment by 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. 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 intention-to-treat analysis which used 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 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%; $p<0.001$). In the per-protocol analysis, change in IPSS was -7.56 at 5 years (-35.9%; 95% CI, -44% to -27%). Significant improvements, when compared with baseline, continued to be reported for scores associated with quality of life, Qmax, and BPH-II.

Subsection Summary: LIFT Study
The LIFT RCT compared PUL with a sham procedure in individuals who were washed out of BPH medications before enrollment. The PUL procedure was associated with greater improvements in lower urinary tract symptoms compared with sham; additionally, the PUL procedure was found to have not worsened sexual function after 3 months of follow-up. After 3 months, patients were given the option to have PUL surgery and about 80% of the sham patients had PUL. Functional improvements, when compared with baseline, appear durable in patients over 2 years and are consistent with the BPH6 study. Follow-up over 3 to 5 years was notable for a high number of patients who were either excluded or lost.

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 analysis of the individual aspects of the composite score. PUL demonstrates measurable improvements in urinary symptoms to 2 years, and is superior to TURP in preserving sexual 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 and preserved sexual function relative to patients receiving sham treatment. 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; there was a high number of patients who were either excluded or lost to follow-up during this time.

Summary
For individuals who have lower urinary tract obstruction symptoms (due to BPH) and receive a PUL, the evidence includes systematic reviews, randomized controlled trials, and noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One randomized controlled trial, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate and reported that the PUL procedure was noninferior for the study's composite end point, which required concurrent fulfilment of 6 independently validated measures of symptoms, safety, and sexual health. While transurethral resection of the prostate was superior to PUL in managing

lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. PUL was further superior to transurethral resection of the prostate in preserving sexual function. These findings were corroborated by another randomized controlled trial, entitled 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 that functional improvements were durable over 3-, 4-, and 5-year follow-ups in a subset of patients treated with PUL; there was a high number of exclusions and loss to follow-up in that group. The evidence is sufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence published interventional procedural guidance on urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. These guidelines state: "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 2015, NICE published a medical technology guidance on use of UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. The guidelines state: "the UroLift system is effective in relieving symptoms of benign prostatic hyperplasia" and "the UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe."

American Urological Association

The American Urological Association (2018) published guidelines on the surgical management of LUTS attributed to BPH. The guidelines made the following recommendations and statements regarding PUL.

- "Clinicians should consider PUL [prostatic urethral lift] as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume <80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP [transurethral resection of the prostate]."
    - "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"

    - "… the quality of evidence for nonserious harms related to the procedure was rated low, while that for incontinence, need for reoperation, and serious harms related to treatment was rated very low."
    - "… patients selecting PUL should be informed that this is a relatively new intervention for LUTS/BPH with uncertainties in long-term durability, though such uncontrolled data are available."
- PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of with LUTS attributed to BPH."
    - "Conditional Recommendation; Evidence Level: Grade C indicating "Risks/Burdens unclear; alternative strategies may be equally reasonable. Better evidence likely to change confidence"

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

Key Words:
Prostate, LIFT, Prostatic urethral lift, BPH, benign prostatic hyperplasia, BPH6, NeoTract UroLift System, Urolift, PUL

Approved by Governing Bodies:
One implantable transprostatic tissue retractor system has been cleared for marketing by FDA through the 510(k) process. The NeoTract UroLift System UL400 (NeoTract, Pleasanton, CA) received clearance in December 2013 (after receiving clearance through FDA's de novo classification process in March 2013; K130651/DEN130023). In March 2016, FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to benign prostatic hyperplasia in men age 50 years and older. FDA product code: PEW.

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:
CPT Codes:

52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)

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Policy History:

Medical Policy Panel, August 2015
Medical Policy Group, August 2015 **(4)**: New policy adopted from Association. Procedure previously considered
Medical Policy Panel, August 2016
Medical Policy Group, August 2016 (**4**): Update to Description, Key Points and References; no change to policy statement investigational.
Medical Policy Panel, December 2017
Medical Policy Group, March 2018 **(4):** Update to Description, Policy, Key Points, Key Words, and References. Policy statements updated to include coverage for PUL effective 3/1/18.
Medical Policy Administrative Committee March 2018
Available for comment March 2 through ~~April 15, 2018~~ (extended to) April 25, 2018
Medical Policy Panel, August 2018
Medical Policy Group, October 2018 **(4):** Updates to Description, Policy, Key Points, and References. Clarified policy statement regarding persistent or progressive lower UTI symptoms "despite medical therapy". Intent unchanged.