Treatments for Benign Prostatic Hyperplasia (BPH)

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DESCRIPTION

Benign prostatic hyperplasia (BPH) is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. The prevalence and the severity of lower urinary tract symptoms (LUTS) in the aging male can be progressive and is an important diagnosis in the healthcare of patients and the welfare of society. In the management of bothersome LUTS, it is important that healthcare providers recognize the complex dynamics of the bladder, bladder neck, prostate, and urethra. Further, symptoms may result from interactions of these organs as well as with the central nervous system or other systemic diseases (e.g., metabolic syndrome, congestive heart failure). Despite the more prevalent (and generally first line) use of medical therapy for men suffering from LUTS attributed to BPH (LUTS/BPH), there remain clinical scenarios

where surgery or minimally invasive procedure is indicated as the initial intervention for LUTS/BPH and should be recommended, providing other medical comorbidities do not preclude this approach *(American Urological Association 2021)*.

Benign prostatic hyperplasia (BPH) results in benign prostatic enlargement (BPE) in some but not all men. This enlargement can in turn lead to benign prostatic obstruction (BPO) and bladder outlet obstruction (BOO). While BPH alone does not require treatment, BPE and BPO are often associated with lower urinary tract symptoms (LUTS), which may require treatment.

BPH can be asymptomatic, and the correlation between symptoms and the presence of prostatic enlargement on physical examination or transrectal ultrasonographic assessment is poor. When symptomatic, BPH presents with lower urinary tract symptoms (LUTS). Typical manifestations of LUTS/BPH include:

- Storage (irritative symptoms): Urinary frequency, urgency, nocturia and incontinence.
- Voiding symptoms: Slow urinary stream, straining to void, urinary intermittency (stream starting and stopping during micturition) or hesitancy, splitting of the voiding stream and terminal dribbling.

Symptoms tend to progress gradually over a period of years, especially in older patients; however, they may improve spontaneously in a minority of patients. Potential complications of untreated BPH include acute urinary retention. In addition, chronic obstruction, and failure to completely empty the bladder of urine can increase the risk of urinary tract infections (UTIs), bladder stones, formation of bladder diverticuli, and renal damage.

BPH is not a risk factor for prostate cancer. BPH occurs primary in the central or transitional zone of the prostate, whereas prostate cancer originates primarily in the peripheral part of the gland. An analysis from a placebo arm of the Prostate Cancer Prevention Trial, where routine biopsies were performed, did not find an association between BPH and prostate cancer.

Many other urologic conditions can present with lower urinary tract symptoms (LUTS). Before concluding that LUTS is related to BPH, other disorders that can cause these symptoms should be excluded by history, physical examination, and selected laboratory and urologic tests. Validated questionnaires should be utilized to measure symptoms severity, symptom bother and to document response to medical or surgical therapies. The most commonly used are the AUA Symptom Index (AUA-SI) and the International Prostate Symptoms Score (IPSS). One of these should be obtained at each visit.

The diagnosis of lower urinary symptoms (LUTS/benign prostate hyperplasia (BPH) is established by the presence of storage, voiding, and/or irritative urinary symptoms in the absence of history, examination or laboratory findings suggesting of non-BPH causes of LUTS. The diagnosis does not require a histologic confirmation.

The choice of available procedures should be based on the size and shape of the prostate gland (i.e., the size and shape of the prostate gland limits the applicability of some procedures), the patients bleeding risk, presentation (i.e., current stones, symptom severity), and the individual's attitude toward potential sexual side effects. Equally important is the treating urologic surgeon's experience and preference. All patients should be provided with the risk/benefit profile of all treatment options to allow them to make informed decisions regarding their treatment plan.

Surgical treatment of BPH may be classified into three general types:

- MIST (minimally invasive surgical treatment)
- Simple prostatectomy
- Transurethral surgery

A variety of alternatives to the standard monopolar TURP have been developed, including bipolar TURP and various laser-based therapies, to achieve similar clinical efficacy while reducing the risks of perioperative bleeding and short- and long-term complications. In appropriate patients for whom the physical size of the prostate cannot address due to the expertise of the surgeon via a safe or efficacious transurethral approach, simple prostatectomy (i.e., adenoma enucleation) may be considered using an open, laparoscopic, or robotic-assisted approach. Finally in select patients, recent innovations in MIST allow for office-based treatments that obviate the need for regional or general anesthesia, hospital stay, discontinuation of anticoagulation therapy and surgery.

Based on the updated 2021 guidelines for the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia by the American Urological Association the panel evaluated the commonly used surgical procedures and MIST to treat LUTS/BPH when indicated based on evaluation by an appropriately trained clinician. These procedures include monopolar and bipolar transurethral resection of prostate (TURP), robotic simple prostatectomy (retropubic, suprapubic, and laparoscopic), transurethral incision of the prostate (TUIP), bipolar transurethral vaporization of the prostate (TUVP), photo selective vaporization of the prostate (PVP), prostatic urethral lift (PUL), thermal ablation using transurethral microwave therapy (TUMT), water vapor thermal therapy (WVTT), transurethral needle ablation (TUNA), laser enucleation using Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP), robotic waterjet treatment (RWT) and prostate artery embolization (PAE). The data utilized to generate the guideline statements *(See Practice Guideline and Position Statements below)* are based on results from what the Panel felt were acceptably performed RCTs and CCTs comparing technique to TURP or sham.

Recommendations for follow-up after initiating medical therapy for bothersome LUTs/BPH remain undefined. Time intervals, tests to be conducted, and consequences of changes in parameters such as IPSS, QoL score, flowrate recordings or residual urine volume have not been systematically studied in the literature. For shorter duration of

onset drugs such as alpha blockers, beta-3 agonists, PDE5s and anticholinergics the first follow-up visit can be as early as four-weeks. For longer acting drugs such as 5-ARIs, the first follow-up visit may be within three to six months if adverse events do not necessitate an earlier visit.

Therapy should not be continued if patients are neither satisfied nor show a decrease in IPSS, per the AAU 2021 guideline in the management of BPH states patients with bothersome LUTS/BPH who elect initial medical management and do not have symptom improvement and/or experience intolerable side effects should undergo further evaluation and consideration of change in medical management or surgical intervention.

Clinical Context and Therapy Purpose
The purpose of minimally invasive procedures in patients who have lower urinary tract symptoms due to benign prostatic hyperplasia (BPH) is to provide treatment options that is an alternative to or an improvement on existing therapies such as medical management or transurethral resection of the prostate (TURP).

Populations
The relevant population of interest is genotypical 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 commonly used surgical procedures and MIST to treat LUTS/BPH when indicated based on evaluation by an appropriately trained clinician. These procedures include the following:

- Monopolar and bipolar transurethral resection of prostate (TURP)
- Robotic simple prostatectomy (retropubic, suprapubic, and laparoscopic)
- Transurethral incision of the prostate (TUIP)
- Bipolar transurethral vaporization of the prostate (TUVP)
- Photo selective vaporization of the prostate (PVP)
- Prosthetic urethral lift (PUL)
- Thermal ablation using transurethral microwave therapy (TUMT)
- Water vapor thermal therapy (WVTT)
- Transurethral needle ablation (TUNA)
- Laser enucleation using holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP)
- Robotic waterjet treatment (RWT)
- Prostate artery embolization (PAE)

Comparators
The following practices are currently being used to treat BPH in this setting: 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 photo selective 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.

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

Cryosurgical Ablation

Cryosurgical ablation for treatment of BPH is not addressed in current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) and no published controlled or uncontrolled studies evaluating this procedure for treating BPH were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Endoscopic Balloon Dilation of the Prostatic Urethra

Endoscopic balloon dilation for treatment of BPH involves the insertion of a balloon catheter tip through the urethra into the prostatic channel where it is inflated to stretch the urethra narrowed by the prostate. Based on the research, endoscopic balloon dilation has been inadequately studied with limited controlled trials, few long-term studies, and fallout in enthusiasm for this treatment. Endoscopic balloon dilation for treatment of BPH is not mentioned in the current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Laser Based Procedures

Laser-based prostatectomy procedures including potassium-titanyl-phosphate photo vaporization, holmium laser procedures and GreenLight laser vaporization have been evaluated in comparative trials and found to compare favorably to TURP. The data in the peer-reviewed medical literature suggests that these procedures may provide improvement in BPH symptoms, voiding function, and urinary retention, in addition to comparing favorably in the long-term to TURP with equally low complication rates.

The American Urological Association (AUA) updated their guideline regarding management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) in 2021 and includes the following regarding laser enucleation:

- Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the

clinician's expertise with these techniques, as prostate size- independent options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

Summary of Evidence
Per the AUA endoscopic enucleation, particularly with laser energy, has clearly become an accepted modality. Published studies show promise with these modalities. The evidence is sufficient in determining that the technology results in an improvement in the net health outcome.

Prostatic Arterial Embolization (PAE)
Prostatic arterial embolization **(**PAE) has been proposed as a treatment for BPH to reduce the blood supply of the prostate gland, which results in some of the gland undergoing necrosis with subsequent shrinkage. The procedure is performed with the individual under local anesthetic using a percutaneous transfemoral approach. Embolization is achieved using microparticles (such as gelatin sponge, polyvinyl alcohol [PVA], and other synthetic biocompatible materials) introduced by super-selective catheterization to block small prostatic arteries.

In 2020, Pisco et. al. in a single-blind sham-controlled crossover RCT evaluated prostatic arterial embolization (PAE) in the treatment of severe lower urinary tract symptoms (LUTS) due to BPH. The study included 80 individuals with severe lower urinary tract symptoms (LUTS) due to BPH, an IPSS of at least 20 and a quality of life (QoL) score of at least 3, who had failed at least 6 months of medical treatment. (The QoL instrument used was not discussed). Individuals, who were blinded to group assignment, were randomized to PAE (n=40) or sham treatment (n=40). Primary efficacy outcomes were assessed at 6 months and then participants in the sham group were able to crossover and receive PAE. Co-primary endpoints were change in IPSS and QoL at 6 months. At 6 months, IPSS decreased 5.03 ([standard deviation] SD, 8.13) points in the sham group and 17.1 (SD, 7.25) in the PAE group, significantly favoring the PAE group ($p<0.0001$). Mean QoL scores at 6 months were 3.48 (SD, 1.38) in the sham group and 1.35 (SD, 1.12) in the PAE group, with a significantly higher QoL score in the PAE group, $p<0.0001$. All 38 individuals in the sham group who completed the single-blind phase crossed-over and received PAE. Reporting of adverse events included all of the data through 12 months. Adverse events were reported in 13 individuals (32.5%) in the sham group over 6 months and in 14 (35%) of individuals who initially underwent PAE and 11 (28.9%) of individuals after crossing over to PAE. Among the adverse events reported after PAE, 86.2% were grade 1, 3 (10.3%) were grade 2 and 1 (3.4%) was grade 3. The latter consisted of expelled small prostate fragments leading to hematuria and acute urinary retention.

several RCTs have compared prostatic arterial embolization (PAE) with TURP. These included superiority trials (Gao, 2014; Radwan, 2020) and inferiority trials (Abt, 2018; Insausti, 2020). The superiority trial by Gao (2014) included individuals with LUTS due to BPH who had an IPSS score greater than 7, a prostate volume of 20-100 mL and peak

urinary flow of less than 15 mL per second. A total of 114 individuals were randomized to PAE (n=57) or TURP (n=57). Participants were followed for a mean of 22.4 months. Efficacy outcomes included IPSS, quality of life, peak urinary flow, and post-voiding residual urine volume. At the 1- and 3-month follow-ups, there was significantly greater improvement in these outcomes in the TURP group. At all time-points, there was significantly greater reduction in prostate volume in the TURP group. A significantly higher percentage of individuals in the PAE group had complications; most of these were minor complications. In the PAE group, there were 22 (38.6%) minor complications and 8 (14%) major complications whereas in the TURP group, there were 13 (22.8%) minor complications and 4 (7%) major complications. Technical and clinical treatment failure were included in the calculation of major complication.

In 2020, Radwan et. al. randomized 60 individuals with LUTS due to BPH and an IPSS Score greater than 7 to monopolar TURP (M-TURP) (n=20), bipolar TURP (B-TURP) (n=20) or PAE. At the 6-month follow-up, improvement in IPSS was significantly higher in each of the TURP groups compared with PAE. The score improved 18, 18 and 14 points in the M-TURP, B-TURP and PAE groups, respectively. Similarly, mean prostate size reduction was 31, 37 and 11 grams in the M-TURP, B-TURP and PAE groups, with a significantly greater reduction ($p<0.001$) in each of the TURP groups compared with the PAE group.

In 2020, Insausti et. al. included 45 individuals with LUTS due to BPH that was refractory to at least 6 months of medical treatment, who had an IPSS score of at least 8 and a peak flow rate (Qmax) less than 10 mL/s or urinary retention. Participants were randomized to receive PAE (n=23) or TURP (n=22). The non-inferiority analysis was based on Qmax at 12 months; a difference of 2 ml/s between groups was considered clinically relevant. At 12 months, the difference between groups in Qmax was 3.31 mL/s (95% CI, -1.84 to 8.46), favoring the TURP group and exceeding the non-inferiority margin of 2 mL/s. The authors stated that the study was underpowered in the non-inferiority comparison because they were not able to retain at least 25 participants per group. During the 12-month study period, IPSS decreased 21.0 points in the PAE group and 18.2 points in the TURP group. This was not a statistically significant difference ($p=0.080$) and a non-inferiority analysis was not done on the IPSS variable. Overall, there were significantly more adverse events reported in the PAE group than the TURP group ($p<0.001$), with more grade 1 events in the TURP group and more grade 2 events in the PAE group. There was 1 individual with urethral stricture in the TURP group and, in the PAE group, 1 individual with rectal ischemia and 1 with radiodermatitis.

The published literature on prostatic arterial embolization (PAE) has been summarized in several systematic reviews and meta-analyses (Jiang, 2019; Knight, 2020; Malling, 2019; Xu 2020). Xu and colleagues included four RCTs and five nonrandomized comparative trials comparing TURP and PAE. In a pooled analysis of data from the nine trials, improvement in IPSS was significantly higher in the TURP group compared with the PAE group (mean difference=2.50, $p=0.0004$). In a similar analysis of Qmax, the TURP group had greater improvement of Qmax than those in the PAE group (mean difference=2.54, $p=0.001$). Data on adverse events were available for seven trials. In a

pooled analysis, overall complication rates did not differ significantly between groups. However, the rate of postoperative sexual dysfunction was significantly lower in the PAE group compared with the TURP group.

Another 2020 meta-analysis, by Knight et. al., included four RCTs and two non-randomized comparative studies comparing prostatic arterial embolization (PAE) and TURP. In a meta-analysis of the RCTs only, the TURP group had significantly higher improvements in Qmax (mean difference=6.17 mL/s, p=0.0002), prostate volume (mean difference=16.2 mL, p=0.0008) and PSA (mean difference=1.02 ng/mL, p=0.02). The pooled analysis did not find a statistically significant difference between groups in IPSS (mean difference -1.36 points, p=0.56). There were significantly more reported adverse events in the TURP group, compared with the PAE group, but not a statistically significant difference between groups in severe adverse events.

Abt et. al. (2018) included 103 individuals with refractory LUTS due to BPH who were randomized to undergo prostatic arterial embolization (PAE) (n=48) or TURP (n=51). Non-inferiority for the primary outcome was defined as less than a 3-point difference in IPSS improvement at 12 weeks. From baseline to 12 weeks, change in the IPSS was -9.23 points after PAE and -10.77 after TURP. Although the difference between groups was less than 3 points, the authors stated that non-inferiority could not be established owing to the large variation among individual outcomes (95% confidence interval for mean difference1.45 to 4.52 points. Functional outcomes at 12 weeks favored the TURP group. The risk of one or more treatment-related adverse events was similar in the 2 groups but more individuals in the TURP group had 2 or more treatment-related adverse events.

Summary of Evidence
Based on the peer reviewed medical literature and current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) the current evidence is insufficient, the benefit over risk remains unclear and prostatic arterial embolization (PAE) is not recommended outside the context of clinical trials. The is insufficient to determine that the technology results in an improvement in the net health outcome.

Prostatic Urethral Lift (PUL) System (Urolift)
Several systematic reviews on prostatic urethral lift (PUL) system (Urolift) have been published. They include a similar set of trials and noncomparative studies.

In 2019, Jung et. al. published a Cochrane systematic review of PUL parallel-group RCTs published up to Jan 2019. The 2 included RCTs (N=297) were the LIFT and BPH6 trials described in detail in the following section. 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).

Two randomized controlled trials (RCTs) of prostatic urethral lift (PUL) system (Urolift) have been performed. Brief description of each trial is provided in the below table:

Study; Trial	Countries	Sites	Dates	Inclusion Criteria		Interventions, n	
					Baseline Prostate Volume, cm^3	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, without median lobe obstruction	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, without median lobe obstruction	30-77	PUL=140	Sham=66

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.

Summary of Evidence from the BPH6 Study

Outcomes	**3 Months**		**12 Months**		**24 Months**	
	PUL	**TURP**	**PUL**	**TURP**	**PUL**	**TURP**
Mean change in IPSS						
n	42	34	40	32	37	32
Mean (SD)	-11.7 (8.5)	-11.8 (9.5)	-10.9 (7.9)	-15.4 (6.8)	-9.2 (9.2)	-15.3 (7.5)
p	<.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

Outcomes	3 Months		12 Months		24 Months	
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
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).
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.[35,] 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.

LIFT Study

Roehrborn et al (2013) reported on results of the pivotal LIFT study, an RCT comparing PUL with sham control among 206 individuals ages 50 years and older with lower urinary tract symptoms secondary to BPH. 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. 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.

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).
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.

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					
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
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) 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 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
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% confidence interval [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).

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. 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.

Follow-up of Prostatic Urethral Lift-Assigned Participants
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 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.

Roehrborn et al (2016) reported on 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% 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 (2015) reported on 3-year results from patients randomized to PUL in the LIFT study. 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.

For individuals who have lower urinary tract obstruction symptoms due to BPH who have had a prior PUL procedure who are treated with a repeat PUL, the evidence includes long-term follow-up data from the LIFT study, a systematic review, and reports on care setting real world experience. Clinical data on the occurrence of repeat PUL, and consensus on clinically relevant definitions of retreatment/reintervention and subsequent outcomes are lacking. The 5-year surgical reintervention rate in the LIFT study was reported as 13.6%, while a meta-analysis concluded that the surgical reintervention rate following PUL is 6% per year. An 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. Per UpToDate (Accessed September 2022), “In a systematic review and meta-analysis the annual surgical reintervention rate after PUL was about 6%; reintervention mainly consisted of TURP(51%), re-PUL (33%) and device explanation (20%). Higher rates were reported with longer follow up.” Therefore repeat PUL would be deemed medically necessary.

Noncomparative 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.

Rukstalis et al (2019) reported results of the MedLift study, the study used to support the expansion of the FDA clearance for PUL to include obstructive median lobes. 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 and results are shown in below tables. One patient required surgical retreatment and no implants were removed over the 12 months of follow-up.

Summary of Characteristics of Key Non-Comparative Studies

Study	Country	Sites	Participants	Treatment Delivery	Follow-Up
Rukstalis (2019)	US	9	n=45 Men ages 50+ with IPSS>13, Qmax ≤12 mL/s, 30 to 80 cc intraurethral prostatic volume, and OML[a]	UroLift PUL procedure with median lobe deployment	12 months

IPSS: International Prostate Symptom Score; 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.

Summary Results of Key Non-Comparative Studies

Study	IPSS	IPSS QOL	Qmax	SHM
Rukstalis (2019)	At 12 m	At 12 m	At 12 m	At 12 m
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

PSS: International Prostate Symptom Score; Qmax: mean peak urinary flow rate; QOL: quality of life; SHIM: Sexual Health Inventory for Men; SD: standard deviation.

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. Results were not presented stratified by prostate volume.

Eure et al (2019) 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.

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.

For individuals who have lower urinary tract obstruction symptoms due to BPH who have had a prior PUL procedure who are treated with a repeat PUL, the evidence includes long-term follow-up data from the LIFT study, a systematic review, and reports on care setting real world experience. The 5-year surgical reintervention rate in the LIFT study was reported as 13.6%, while a meta-analysis concluded that the surgical reintervention rate following PUL is 6% per year. An 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. Also, per UpToDate (Accessed September 2022), “In a systematic review and meta-analysis the annual surgical reintervention rate after PUL was about 6%; reintervention mainly consisted of TURP(51%), re-PUL (33%) and device explanation (20%). Higher rates were reported with longer follow up.” Therefore, repeat PUL is deemed medically necessary.

Summary of Evidence
For individuals who have 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 and receive a PUL, the evidence includes systematic reviews, RCTs, and noncomparative studies. One RCT, the BPH6 study, compared the PUL procedure with TURP and reported that the PUL procedure was noninferior for the study's composite endpoint, which required concurrent fulfillment of 6 independently validated measures of symptoms, safety, and sexual health. While TURP was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over 2 years. Prostatic urethral lift was further superior to TURP in preserving ejaculatory function. These findings were corroborated by another RCT (the LIFT study), which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at 3 months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported these findings were preserved in a subset of patients over 3 to 5 years; however, a high

number of patients were either excluded or lost to follow-up during this time. The BPH6 and LIFT RCTs included men with a prostate volume up to 80 cm^3 and excluded men with median lobe obstruction. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Temporary Prostate Stents
A temporary prostatic stent, The Spanner (SRS Medical, North Billerica, MA), received premarket approval (PMA) from the FDA based on a multicenter, prospective, randomized clinical trial designed to evaluate the safety and effectiveness of The Spanner to manage LUTS and bladder emptying following TUMT treatment after an initial period of catheterization. Based on the study results, the FDA indicated the device is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization.

A randomized controlled trial (RCT) evaluating The Spanner included 186 individuals who were 45 years of age and older. A total of 100 subjects who received The Spanner and 86 subjects in a control group were studied for changes in IPSS, PVR, and adverse events. Both groups were evaluated at 1-, 2-, and 4-week intervals during The Spanner indwelling period and at 2 and 4 weeks after The Spanner removal. Beginning with preoperative IPSS scores of approximately 22 points, The Spanner group score decreased by 7.28 points compared to 4.42 points in the control group, a difference of 2.86 points ($p=0.019$). However, although evaluation at the 1-week interval revealed a significant difference of 3 points between the groups ($p=0.047$), at 2 weeks and at subsequent visits, this was no longer the case ($p=0.084$ at 2 weeks). Mean PVR was significantly less in The Spanner group compared to controls up to 4 weeks following randomization, with the mean decrease from pre-insertion baseline being 6.5 mls in The Spanner group versus a 28.5 ml increase in the control group. However, after 4 weeks there was no significant difference in PVR between the groups. The most notable limitation of this study is the lack of long-term follow-up, as uroflowmetry, PVR, and IPSS data was only collected up to 1 week following stent removal; therefore, the durability of the results is not evident.

The FDA summary reported the majority of adverse events, greater than 75% for both groups, occurred during weeks 1 to 4 following insertion. Adverse events also occurred following removal of the device and included bleeding/hematuria, urinary frequency/retention/urgency, perineal pain, and symptomatic urinary tract infection. There were 385 adverse events reported by 99 subjects in The Spanner group and 273 adverse events reported by the 80 control group subjects. The study results are limited in demonstrating meaningful improvement in clinical outcomes in the group that received the temporary prostatic stent compared to the subjects studied who had a successful voiding trial after BPH surgery. The clinical significance of decreased IPSS scores at 1 week only with a difference of 3 points at that visit is questionable as is the difference in PVR noted up to 4 weeks, in the absence of increased urinary tract infections or other PVR-related adverse effects in the control group compared to The Spanner group. On the

other hand, perineal pain was noted to occur more frequently in The Spanner treated group.

Summary of Evidence
Based on the peer reviewed medical literature the safety and/or effectiveness regarding the use of a of temporary prostatic stent due to benign prostatic hyperplasia (BPH) has not been established to manage lower urinary tract symptoms (LUTS) and bladder emptying following TUMT treatment after an initial period of catheterization. Further randomized controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transurethral Incision of the Prostate (TUIP)
A randomized controlled trial (RCT) compared TUIP and TURP in 120 individuals with bladder outlet obstruction secondary to BPH. For individuals in the study, the estimated resectable weight of the prostates was less than 20g. After a mean follow-up time of 34 months, similar improvements were seen in urinary peak flow rates in the two groups. There were no statistically significant differences between groups pre-operatively or at any post-operative follow-up in irritation, obstruction, or symptom scores. Post-operative retrograde ejaculation was significantly more common in the TURP group compared with the TUIP group.

The current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) includes the following: TUIP should be offered as an option for patients with prostates $\leq$ 30cc for the surgical treatment of LUTS/BPH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transurethtral Microwave Thermotherapy (TUMT)
Transurethral microwave thermotherapy **(**TUMT) was one of the earliest office-based MISTs available and several iterations have been modified since it was first described over 25 years ago. TUMT is a process whereby coagulation necrosis of the prostatic tissue is achieved by transferring energy into the tissue and creates heat. A specialized catheter with a cooling component is placed transurethrally into the prostatic fossa, as well as a rectal catheter that measures temperature, and a microwave antenna heats the prostatic tissue to a minimum 45°C. As the prostate shrinks over the ensuing weeks, the channel opens up.

A 2012 Cochrane review on Transurethral microwave thermotherapy (TUMT) for treatment of BPH identified 6 RCTs comparing TUMT and TURP and 8 RCTs comparing TUMT to sham treatment. Compared with sham treatment, TUMT significantly improved urinary symptom scores and peak urinary flow. In a pooled analysis the mean urinary symptom scores decreased by 65% with TUMT and 77% with TURP. Although improved in both groups, symptom improvement was significantly higher with TURP. Peak urinary flow also increased significantly more in the TURP group and there was a significantly lower risk of dysuria, urinary retention, and re-

treatment for BPH. However, compared with TURP, TUMT was associated with significantly decreased risks for retrograde ejaculation, hematuria, blood transfusions and treatment for strictures.

The current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) includes the following: TUMT may be offered as a treatment option to patients with LUTS/BPH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transurethral Radiofrequency Needle Ablation or Transurethral Needle Ablation (TUNA)

Based on the current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) the Panel searched for studies regarding transurethral radiofrequency needle ablation or transurethral needle ablation (TUNA) meeting their updated inclusion criteria and none were identified. Based on the lack of peer reviewed public literature and TUNAs substantially diminished clinical relevance, the Panel does not recommend TUNA in the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Transvaporation of the Prostate (TUVP)

Transvaporation of the prostate (TUVP) of the prostate is a technical electrosurgical modification of the standard TURP. TUVP can utilize a variety of energy delivery surfaces including a spherical rolling electrode (rollerball), grooved roller electrode (vaportrode), loop electrode, or hemi-spherical/oval mushroom electrode (button), amongst others. TUVP typically uses saline and is powered with a bipolar energy source. Compared to traditional resection loops, the various TUVP designs aspire to improve upon tissue visualization, blood loss, resection speed and patient morbidity.

A meta-analysis identified 20 prospective clinical trials comparing TUVP and TURP. The study found that, after 12 months, outcomes including urinary symptom scores and peak urinary flow rates were similar in the TUVP and TURP groups. TUVP was associated with a shorter operative duration and shorter hospital stay and TURP was associated with a lower rate of post-operative urinary retention and lower reoperation rates.

Summary of Evidence

Based on review of the peer reviewed medical literature clinical trials comparing TUVP and TURP found that outcomes including urinary symptom score and peak urinary flow rates were similar in the TUVP and TURP groups. The current 021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) includes the following: bipolar TUVP may be offered as an option to patients for the treatment of LUTS/BPH. The is

insufficient to determine that the technology results in an improvement in the net health outcome.

Water Induced Thermotherapy (WIT)
Water-induced thermotherapy (WIT) (also known as hot water balloon thermoablation or thermourethral hot water therapy). No published randomized controlled trials (RCTs) have addressed WIT. WIT has only been evaluated in cases studies; these have found that the treatment can relieve the symptoms of BPH but lack control or comparison groups. Further randomized controlled trials are needed to determine safety and efficacy. The current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) does not mention the use of water-induced thermotherapy (WIT). Further randomized controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Waterjet Tissue Ablation
Waterjet tissue ablation, also known as Aquablation®, is a robotically executed procedure to resect and remove prostate tissue using a pressurized heat-free waterjet. Aquablation is delivered with the AquaBeam® Robotic System for resection and removal of prostate tissue in individuals with LUTS due to BPH.

One RCT has been published; this is a double-blind non-inferiority trial comparing Aquablation (n=117) to TURP (n=67) (Gilling 2018; Gilling 2019). Eligibility included age 45 to 80. The primary outcome was the noninferiority of Aquablation to TURP on 6-month mean change in IPSS. The noninferiority margin was 4.7 points on the IPSS. Baseline IPSS scores were 22.9 in the Aquablation group and 22.2 n the TURP group. At 6 months, the IPSS decreased 16.9 points in the Aquablation group and 15.1 n the TURP group, establishing non-inferiority as well as superiority. Moreover, 90% of the Aquablation group and 79% of the TURP group had at least a 50% decrease in IPSS. Gilling 2019 reported 1-year outcomes. Mean IPSS reduction at 12 months was 15.1 in the Aquablation group and 15.1 in the TURP group, p=0.9898. Mean percent reduction in IPSS score was also the same in both groups, 67%. Mean maximum urinary flow rates and mean reduction in post-void residual volume were similar in the two groups at 12 months. The primary safety outcome was the proportion of participants at 3 months with adverse events related to the study procedure that were Clavien-Dindo grade 2 or higher or a grade 1 event resulting in permanent disability (such as incontinence or erectile dysfunction). At 3 months, the safety endpoint was significantly lower in the Aquablation group (26%) than the TURP group (42%), p=0.0149. A total of 20 grade 2 events were reported in 19 individuals undergoing Aquablation compared with 15 Grade 2 events in 11 TURP recipients. Between months 3 and 12, 12 additional adverse events deemed related to the study procedures were reported; rates were similar between groups.

In 2019 Hwang et. al. in a Cochrane review on Aquablation identified only one RCT, the Gilling study described above. The authors concluded, longer-term data and comparisons with other modalities appear critical to a more thorough assessment of the role of

Aquablation for the treatment of LUTS in men with BPH. A 2020 systematic review by Suarez-Ibarrola and et. al. also identified only one RCT, the Gilling study, as well as several single-arm studies.

Summary of Evidence
Based on review of the peer reviewed medical literature the use of Aquablation delivered with the AquaBeam® Robotic System for resection and removal of prostate tissue in individuals with LUTS due to BPH is insufficient, additional randomized controlled trials with longer-term data and comparisons with other modalities appear are needed to assess the safety and efficacy of Aquablation for the treatment of LUTS in men with BPH. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Water Vapor Thermal Therapy (WVTT) (Rezum)
Water vapor thermal therapy (WVTT) utilizes convective radiofrequency to create stored thermal energy in the form of steam, which is delivered transurethrally via a specialized device into the transition zone. The steam travels through the transition zone, denaturing tissue and thereby ablating the adenoma to create an opening.

Kang et. al. (2020) conducted a Cochrane review of transurethral water vapor thermal therapy for management of LUTS in men with BPH. In literature searches conducted through February 2020, the reviewers identified only one RCT (McVary et. al. [2015], The reviewers concluded that there was moderate-to low-certainty evidence that the procedure appears to improve urologic symptom scores and quality of life compared to a sham procedure. However, there was very low certainty of evidence about the effects of the intervention on major adverse events.

A double-blind RCT67-69 (n=197) compared WVTT (also referred to as transurethral destruction of prostate tissue by radiofrequency generated water thermotherapy) with SHAM. Mean age of study participants was 63 years. Patients had a mean baseline IPSS of 22 and a mean prostate volume of 45 cm3. The study excluded men with prostate volume < 30g and > 80g and did not exclude men with obstructing middle lobes or median bars. Response to treatment through 3 months, based on an improvement in IPSS of ≥30% or ≥8 points, was significantly greater in the WVTT group (74%) compared to the SHAM group (31%) (RR: 2.4; 95%CI: 1.6, 3.5). Mean changes from baseline in IPSS and IPSS-QoL at 3 months were greater in the WVTT group compared to the SHAM group with a MDD of >3 points (MD: -6.9; 95%CI: -9.1, -4.8). Three-year results showed sustained improvements for the IPSS IPSS-QoL, and Qmax, with scores remaining significantly improved from baseline; Qmax improvement was > 50% from 3 to 24 months and 39% at 36 months.13 At 36 months in the intent-to- treat population of the original 136 participants, mean change from baseline in IPSS was -11.0 points and the mean score was 10.4 points, representing a 50% improvement from baseline. Mean IPSS-QoL was improved from baseline by 49% at 3 years.

Summary of Evidence
Based on the peer reviewed medical literature and the current 2021 American Urology Association (AUA) guidelines for management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH), includes the following, water vapor thermal therapy (WVTT) using the Rezum system should be considered as a treatment option for patients with LUTS/BPH provided the prostate volume 30-80 cc. The evidence is sufficient in determining that the technology results in an improvement in the net health outcome.

Professional Guidelines and Position Statements

American Urological Association (AUA)
In 2021, the American Urological Association updated their guideline regarding management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH) which includes the following guideline statements:

Evaluation
Initial Evaluation

1. In the initial evaluation of patients presenting with bothersome LUTS possibly attributed to BPH, clinicians should obtain a medical history, conduct a physical examination, utilize the International Prostate Symptom Score (IPSS), and perform a urinalysis. (Clinical Principle)
2. Patients should be counselled on options for intervention, which can include behavioral/lifestyle modifications, medical therapy and/or referral for discussion of procedural options. (Expert Opinion)

Follow-up Evaluation

3. Patients should be evaluated by their providers 4-12 weeks after initiating treatment (provided adverse events do not require earlier consultation) to assess response to therapy. Revaluation should include the IPSS. Further evaluation may include a post-void residual (PVR) and uroflowmetry. (Clinical Principle)
4. Patients with bothersome LUTS/BPH who elect initial medical management and do not have symptom improvement and/or experience intolerable side effects should undergo further evaluation and consideration of change in medical management or surgical intervention. (Expert Opinion)

Preoperative Testing

5. Clinicians should consider assessment of prostate size and shape via transrectal or abdominal ultrasound, cystoscopy, or cross-sectional imaging (i.e., magnetic resonance imaging [MRI]/ computed tomography [CT]) if such studies are available, prior to intervention for LUTS/BPH. (Clinical Principle)

6. Clinicians should perform a PVR assessment prior to intervention for LUTS/BPH. (Clinical Principle)
7. Clinicians should consider uroflowmetry prior to intervention for LUTS/BPH. (Clinical Principle)
8. Clinicians should consider pressure flow studies prior to intervention for LUTS/BPH when diagnostic uncertainty exists. (Expert Opinion)
9. 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. (Clinical Principle)

Medical Therapy

Alpha Blockers

10. Clinicians should offer one of the following alpha blockers as a treatment option for patients with bothersome, moderate to severe LUTS/BPH: alfuzosin, doxazosin, silodosin, tamsulosin, or terazosin. (Moderate Recommendation; Evidence Level: Grade A)
11. When prescribing an alpha blocker for the treatment of LUTS/BPH, the choice of alpha blocker should be based on patient age and comorbidities, and different adverse event profiles (e.g., ejaculatory dysfunction [EjD], changes in blood pressure). (Moderate Recommendation; Evidence Level: Grade A)

Alpha Blockers and Intraoperative Floppy Iris Syndrome

12. When initiating alpha blocker therapy, patients with planned cataract surgery should be informed of the associated risks and be advised to discuss these risks with their ophthalmologists. (Expert Opinion)

5α-Reductase inhibitor (5-ARI)

13. For the purpose of symptom improvement, 5-ARI monotherapy should be used as a treatment option in patients with LUTS/BPH with prostatic enlargement as judged by a prostate volume of > 30cc on imaging, a prostate specific antigen (PSA) > 1.5ng/dL, or palpable prostate enlargement on digital rectal exam (DRE). (Moderate Recommendation; Evidence Level: Grade B)
14. 5-ARIs alone or in combination with alpha blockers are recommended as a treatment option to prevent progression of LUTS/BPH and/or reduce the risks of urinary retention and need for future prostate-related surgery. (Strong Recommendation; Evidence Level: Grade A)
15. Before starting a 5-ARI, clinicians should inform patients of the risks of sexual side effects, certain uncommon physical side effects, and the low risk of prostate cancer. (Moderate Recommendation; Evidence Level: Grade C)

16. Clinicians may consider 5-ARIs as a treatment option to reduce intraoperative bleeding and peri- or postoperative need for blood transfusion after transurethral resection of the prostate (TURP) or other surgical intervention for BPH. (Expert Opinion)

Phosphodiesterase-5 Inhibitor (PDE5)

17. For patients with LUTS/BPH irrespective of comorbid erectile dysfunction (ED), 5mg daily tadalafil should be discussed as a treatment option. (Moderate Recommendation; Evidence Level: Grade B)

Combination Therapy

18. 5-ARI in combination with an alpha blocker should be offered as a treatment option only to patients with LUTS associated with demonstrable prostatic enlargement as judged by a prostate volume of > 30cc on imaging, a PSA >1.5ng/dL, or palpable prostate enlargement on DRE. (Strong Recommendation; Evidence Level: Grade A)
19. Anticholinergic agents, alone or in combination with an alpha blocker, may be offered as a treatment option to patients with moderate to severe predominant storage LUTS. (Conditional Recommendation; Evidence Level: Grade C)
20. Beta-3-agonists in combination with an alpha blocker may be offered as a treatment option to patients with moderate to severe predominate storage LUTS. (Conditional Recommendation; Evidence Level: Grade C)
21. Clinicians should not offer the combination of low-dose daily 5mg tadalafil with alpha blockers for the treatment of LUTS/BPH as it offers no advantages in symptom improvement over either agent alone. (Moderate Recommendation; Evidence Level: Grade C)

Acute Urinary Retention (AUR) Outcomes

22. Physicians should prescribe an oral alpha blocker prior to a voiding trial to treat patients with AUR related to BPH. (Moderate Recommendation; Evidence Level: Grade B).
23. Patients newly treated for AUR with alpha blockers should complete at least three days of medical therapy prior to attempting trial without a catheter (TWOC). (Expert Opinion)
24. Clinicians should inform patients who pass a successful TWOC for AUR from BPH that they remain at increased risk for recurrent urinary retention. (Moderate Recommendation; Evidence Level: Grade C).

Surgical Therapy

25. 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. (Clinical Principle)

26. Clinicians should not perform surgery solely for the presence of an asymptomatic bladder diverticulum; however, evaluation for the presence of bladder outlet obstruction (BOO) should be considered. (Clinical Principle)

Transurethral Resection of the Prostate (TURP)

27. TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

28. Clinicians may use a monopolar or bipolar approach to TURP as a treatment option, depending on their expertise with these techniques. (Expert Opinion)

Simple Prostatectomy

29. Open, laparoscopic, or robotic assisted prostatectomy should be considered as treatment options by clinicians, depending on their expertise with these techniques, only in patients with large to very large prostates. (Moderate Recommendation; Evidence Level: Grade C)

Transurethral Incision of the Prostate (TUIP)

30. TUIP should be offered as an option for patients with prostates ≤30cc for the surgical treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

Transurethral Vaporization of the Prostate (TUVP)

31. Bipolar TUVP may be offered as an option to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B)

Photoselective Vaporization of the Prostate (PVP)

32. PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

Prostatic Urethral Lift (PUL)

33. PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C)

34. 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)

Transurethral Microwave Therapy (TUMT)

35. TUMT may be offered as a treatment option to patients with LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C)

Water Vapor Thermal Therapy (WVTT)

36. WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc. (Moderate Recommendation; Evidence Level: Grade C)

37. WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)

Transurethral Needle Ablation (TUNA)

38. TUNA is not recommended for the treatment of LUTS/BPH. (Expert Opinion)

Laser Enucleation

39. Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician's expertise with these techniques, as prostate size- independent options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)

Robotic Waterjet Treatment (RWT)

40. Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80cc. (Conditional Recommendation; Evidence Level: Grade C)

Prostate Artery Embolization (PAE)

41. PAE for the routine treatment of LUTS/BPH is not supported by current data, and benefit over risk remains unclear; therefore, PAE is not recommended outside the context of clinical trials. (Expert Opinion)

Hematuria

42. After exclusion of other causes of hematuria, 5-ARIs may be an appropriate and effective treatment alternative in men with refractory hematuria presumably due to prostatic bleeding. (Expert Opinion)

Medically Complicated Patients

43. HoLEP, PVP, and ThuLEP should be considered as treatment options in patients who are at higher risk of bleeding. (Expert Opinion)

Traditionally, the primary goal of treatment has been to alleviate bothersome LUTS that result from BPO. More recently, treatment has also focused on the prevention of disease progression and complications such as AUR. Pharmacologic classes of medications used to treat LUTS/BPH include alpha-adrenergic antagonists (alpha blockers), 5-ARIs, PDE5, and anticholinergics, which may be utilized alone or in combination to take advantage of their different mechanisms of action. An additional class of agent that may be considered in combination with alpha blockers is beta-3 agonists.

There also exist clinical scenarios in which conservative management including lifestyle changes (e.g., fluid restriction, avoidance of substances with diuretic properties) or pharmacological management are either inadequate or inappropriate. More recently, long-term use of medications for LUTS/BPH have been implicated in cognitive issues and depression. These situations merit considered of one of many invasive procedures available for the treatment of LUTS/BPH. Indications for these procedures include a desire by the patient to avoid taking a daily medication, failure of medical therapy to sufficiently ameliorate bothersome LUTS, intolerable pharmaceutical side effects, and/or the following conditions resulting from BPH and for which medical therapy is insufficient: acute and/or chronic renal insufficiency, refractory urinary retention, recurrent UTIs, recurrent bladder stones, and recalcitrant gross hematuria. Acute and chronic adverse events are associated with each class of medical therapy and can including cardiovascular and sexual effects.

Patients with bothersome LUTS/BPH who elect initial medical management and do not have symptom improvement and/or experience intolerable side effects should undergo further evaluation and consideration of change in medical management or surgical intervention. (Expert Opinion)

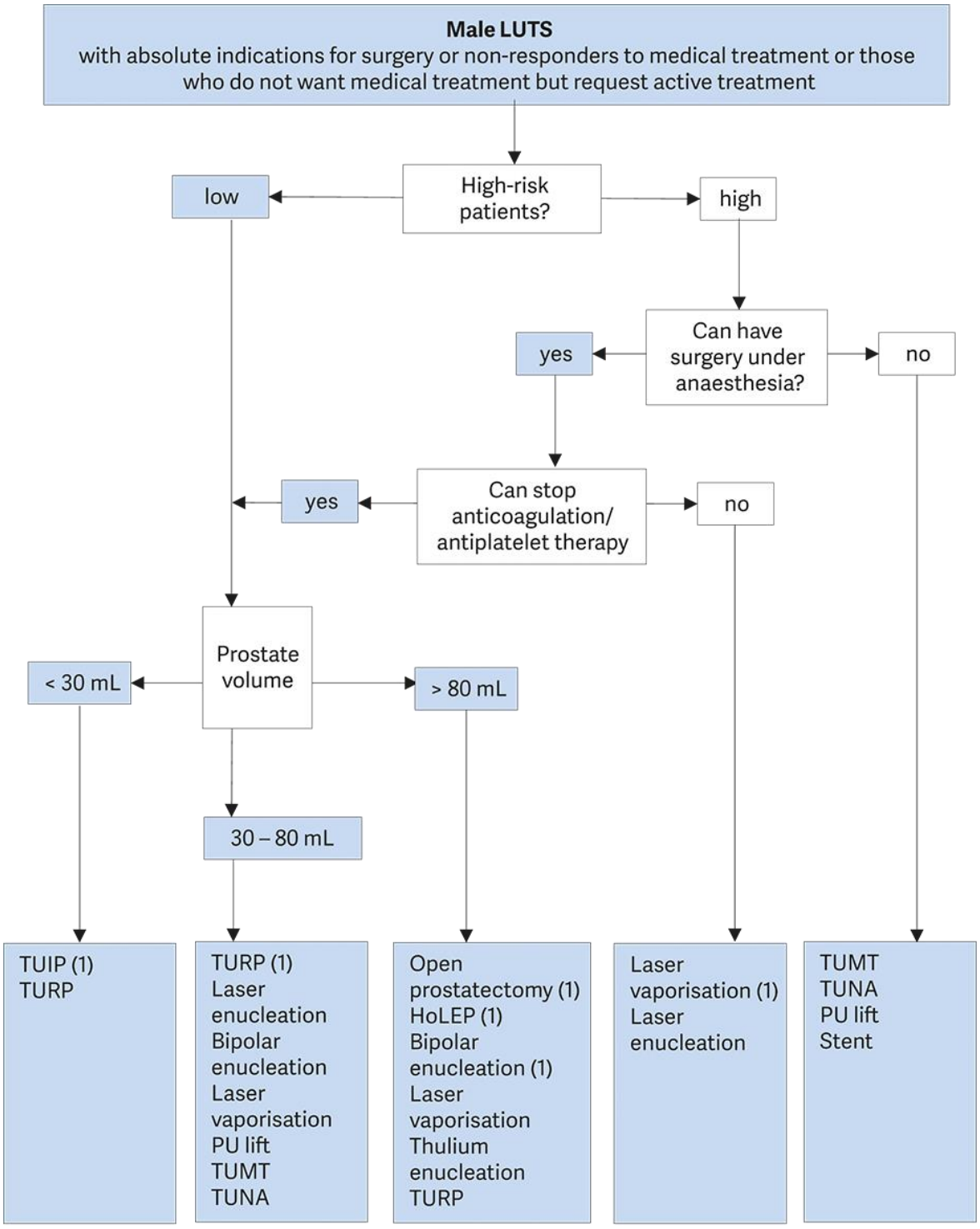
European Association of Urology (2020)
In 2020, the European Association of Urology updated its guidelines The recommendations with grades A from the guideline include:

- Renal function assessment must be performed if renal impairment is suspected, based on history and clinical examination or in the presence of hydronephrosis or when considering surgical treatment for male LUTS.
- Urethrocystoscopy should be performed in men with LUTS to exclude suspected bladder or urethral pathology and/or prior to minimally invasive/surgical therapies if the findings may change treatment.
- Offer men with mild/moderate symptoms, minimally bothered by their symptoms, watchful waiting.
- Offer men with LUTS lifestyle advice prior to or concurrent with treatment.
- Offer a1-blockers to men with moderate-to-severe LUTS.

- Offer 5α-reductase inhibitors to men who have moderate-to-severe LUTS and an enlarged prostate (> 40 mL).
- Offer combination treatment with an α1-blocker and a 5α-reductase inhibitor to men with moderate-to-severe LUTS and risk of disease progression (e.g. prostate volume > 40 mL).
- Use combination treatment of an α1-blocker with a muscarinic receptor antagonist in patients with moderate-to-severe LUTS if relief of storage symptoms has been insufficient with monotherapy with either drug.
- TURP is the current surgical standard procedure for men with prostate sizes of 30-80 mL and bothersome moderate-to-severe LUTS secondary of BPO. TURP provides subjective and objective improvement rates superior to medical or minimally invasive treatments.
- TUIP (transurethral incision of the prostate) is the surgical therapy of choice for men with prostate sizes < 30 mL, without a middle lobe, and bothersome moderate-to-severe LUTS secondary to BPO.
- OP (open prostatectomy) or EEP (endoscopic enucleation of the prostate) such as holmium laser or bipolar enucleation are the first choice of surgical treatment in men with a substantially enlarged prostate (e.g. > 80 mL) and moderate-to-severe LUTS.
- Durability is in favor of TURP which has lower re-treatment rates compared to TUMT (transurethral microwave therapy)
- TUNA™ is a minimally invasive alternative with decreased morbidity compared to TURP but with less efficacy.
- Durability is in favor of TURP with lower re-treatment rates compared to TUNA™
- HoLEP (holmium laser enucleation) and 532-nm laser vaporization of the prostate are alternatives to TURP in men with moderate-to-severe LUTS leading to immediate, objective, and subjective improvements comparable with TURP
- ThuVaRP (Tm:YAG vaporesection) is an alternative to TURP for small- and medium-size prostates.
- Prostatic urethral lift (Urolift®) leads to objective and subjective short- and mid-term improvements. RCTs with longer follow-up are required.

The guideline urethral lift implants, giving a grade B recommendation for the use of Urolift in men with lower urinary tract symptoms who had prostates < 70 mL with no middle lobe and were interested in preserving ejaculatory function. It noted that “long term effects have not been evaluated.”

Treatment algorithm of bothersome LUTS refractory to conservative/medical treatment or in cases of absolute operation indications. The flowchart was stratified by the patient’s ability to have anesthesia, cardiovascular risk, and prostate size.



(1) Current standard/first choice. The alternative treatments are presented in alphabetical order. *Notice*: Readers are strongly recommended to read the full text that highlights the current position of each treatment in detail.

Laser vaporization includes GreenLight, thulium, and diode laser vaporization; Laser enucleation includes holmium and thulium laser enucleation.

HoLEP=holmium laser enucleation; TUIP=transurethral incision of the prostate; TUMT=transurethral microwave therapy; TUNA=transurethral needle ablation; TURP=transurethral resection of the prostate.

Summary of evidence	**LE**
Prostatic urethral lift improves IPSS, Qmax and QoL; however, these improvements are inferior to TURP at 24 months.	1b
Prostatic urethral lift has a low incidence of sexual side effects.	1b
Patients should be informed that long-term effects including the risk of retreatment have not been evaluated.	4

Recommendation	**Strength rating**
Offer Prostatic urethral lift (Urolift®) to men with LUTS interested in preserving ejaculatory function, with prostates < 70 mL and no middle lobe.	Strong

National Institute for Health and Care Excellence (NICE)

In 2021, the National Institute for Health and Care Excellence (NICE) published an updated medical technologies guidance with the following recommendations:

1.1 Evidence supports the case for adopting the UroLift System for treating lower urinary tract symptoms of benign prostatic hyperplasia. The UroLift System relieves lower urinary tract symptoms, avoids risk to sexual function, and improves quality of life.

1.2 The UroLift System is a minimally invasive procedure, which 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.

Clinical-effectiveness overview

UroLift is effective with sustained clinical benefits, and the procedure is minimally invasive

- The committee concluded that UroLift is clinically effective, with sustained relief of lower urinary tract symptoms up to 5 years after treatment. It is implanted using a minimally invasive procedure. The clinical experts confirmed that in their practice, UroLift is an effective treatment that is well tolerated.

Regulatory Status
The UroLift System received FDA authorization for marketing through a de novo classification approval on September 13, 2013 (K130651), as a Class II device. Updated UroLift® System UL400 approval was applied for in 2019 (K193269) and for UroLift Advanced Tissue Control (ATC) System in 2020 (K200441) It is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men aged 45 and above, with contraindications noted.

INDICATIONS FOR USE
The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

CONTRAINDICATIONS
The UroLift System should not be used if the patient has:

- Prostate volume of >100 cc
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

In September 2016, the Rezum™ System (NxThera, Inc, acquired by Boston Scientific in 2018) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K150786). The FDA determined that this device was substantially equivalent to existing devices (Medtronic Prostiva devices). Rezum is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia. It is indicated for men > 50 years of age with a prostate volume >30cm^3 and <80cm^3. The Rezum System is also indicated for the treatment of prostate with hyperplasia of the central zone and/or a median lobe.

A temporary prostatic stent, the Spanner (SRS Medical, North Billerica, MA), received premarket approval (PMA) from the FDA January 2016 based on a multicenter, prospective, randomized clinical trial designed to evaluate the safety and effectiveness of The Spanner to manage LUTS and bladder emptying following TUMT treatment after an initial period of catheterization. Based on the study results, the FDA indicated the device is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization.

In April 2017, the Aquabeam® System (Procept Robotics Corporation) was cleared for marketing by the FDA through the 513(f)(2) (de novo) classification process (DEN170024). The device is intended for the resection and removal of prostate tissue in males suffering from LUTS due to benign prostatic hyperplasia.

In June 2017, The FDA granted a de novo classification to the intravascular implant, Embosphere Microspheres (BioSphere Medical, S.A., France), as a class II biocompatible PAE device for use as a minimally invasive treatment for symptomatic BPH.

December 2021, the FDA approved the Optilume Urethral Drug Coated Balloon (DCB) to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. The device is designed to be used in adult males for urethral stricture of 3cm or less in length.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policy:

- 02.01.53 High Intensity Focused Ultrasound (HIFU)

Medically Necessary

The following procedures may be considered **medically necessary** as an alternative to open prostatectomy or transurethral resection of the prostate (TURP) for the treatment of benign prostate hyperplasia (BPH) when **ALL** the following criteria are met:

One of the following minimally invasive treatments is utilized:

- Holmium laser ablation of the prostate [HoLAP]) (52649); **or**
- Holmium laser enucleation of the prostate [HoLEP] (52649); **or**
- Holmium laser resection of the prostate [(HoLRP] (52649); **or**
- Photoselective vaporization (PVP) (52648); **or**
- Transurethral electro vaporization of the prostate (TUVP); **or**
- Transurethral microwave thermotherapy (TUMT); **or**
- Transurethral incision of the prostate (TUIP) with prostate $\leq$30cc; **or**
- Visually guided laser ablation of the prostate (VLAP), also called non-contact laser ablation of the prostate (52647,52648); **and**

The individual is 45 years or older with one of the following conditions attributed to benign prostatic hyperplasia (BPH):

- Mild to moderate lower urinary tract symptoms (LUTS)
    - Increased urinary frequency
    - Urgency
    - Incontinence
    - Straining
    - Nocturia
    - Decreased and intermittent force of the stream
    - Hematuria

- Sensation of incomplete bladder emptying; **and**

The individual has had an adequate trial of the usual prescribed BPH medication (alpha blockers, beta-3 agonists, PDE5s, anticholinergics, 5-ARIs) and is refractory or intolerant; **and**

The individual has had appropriate testing to exclude diagnosis of prostate cancer within 12 months of the procedure; **and**

The individual is a poor candidate for other surgical interventions for BPH, or the individual opts to undergo a minimally invasive procedure.

Prostatic Urethral Lift (e.g., Urolift) (52441,52442, C9739, C9740)
Prostatic urethral lift (Urolift) for the treatment of urinary outlet obstruction due to benign prostate hyperplasia (BPH) may be considered **medically necessary** when **ALL** the following criteria are met for an initial or repeat procedure:

- The individual is 45 years or older and has a diagnosis of mild to moderate lower urinary tract symptoms (LUTS) secondary to with one of the following conditions attributed to benign prostatic hyperplasia (BPH):
  - Increased urinary frequency
  - Urgency
  - Incontinence
  - Straining
  - Nocturia
  - Decreased and intermittent force of the stream
  - Hematuria
  - Sensation of incomplete bladder emptying; **and**
- The individual's symptoms are caused by enlargement of the later lobes of the prostate with no obstructing medial lobe enlargement present and a prostate volume that is ≤80cc; **and**
- The individual has had an adequate trial of the usual prescribed benign prostatic hyperplasia (BPH) medication (alpha blockers, beta-3 agonists, PDE5s, anticholinergics, 5-ARIs) and is refractory or intolerant; **and**
- The individual is a poor candidate for other surgical interventions for benign prostatic hyperplasia (BPH), or the individual opts to undergo a minimally invasive procedure; **and**
- The individual has had appropriate testing to exclude diagnosis of prostate cancer within 12 months of this procedure.

Prostatic urethral lift (Urolift) for the treatment of urinary outlet obstruction due to benign prostate hyperplasia (BPH) not meeting the above criteria is considered **not medically necessary.**

Water Vapor Thermal Therapy (Rezum) (53854)
Transurethral water vapor thermal therapy (Rezūm) may be considered medically necessary for the treatment of benign prostatic hyperplasia (BPH) when **ALL** the following criteria are met:

The individual is 50 years or older with one of the following conditions attributed to benign prostatic hyperplasia (BPH):

- Mild to moderate lower urinary tract symptoms (LUTS)
    - Increased urinary frequency
    - Urgency
    - Incontinence
    - Straining
    - Nocturia
    - Decreased and intermittent force of the stream
    - Hematuria
    - Sensation of incomplete bladder emptying; **and**

The individual's prostate volume >30cc and < 80cc; **and**

The individual has had an adequate trial of the usual prescribed BPH medication (alpha blockers, beta-3 agonists, PDE5s, anticholinergics, 5-ARIs) and is refractory or intolerant; **and**

The individual has had appropriate testing to exclude diagnosis of prostate cancer within 12 months of the procedure; **and**

The individual is a poor candidate for other surgical interventions for BPH, or the individual opts to undergo a minimally invasive procedure.

Investigational
The following procedures are considered **investigational** because their safety and/or effectiveness in the treatment of urinary outlet obstruction due to benign prostatic hyperplasia (BPH) has not been established by review of the available published peer-reviewed literature:
When the above medical necessity criteria are not met

- Absolute ethanol injections
- Aquablation/transurethral waterjet ablation (e.g., AquaBeam System) (0421T)
- Cryosurgical ablation for the treatment for BPH (55873)
- Drug-coated balloon (e.g., Optilume) (0619T)
- Endoscopic balloon dilation of the prostatic urethra
- High-intensity focused ultrasound (HIFU)
- Histotripsy (Vortx Rx System)
- Interstitial laser coagulation (ILC)
- ITind device implant
- Placement of temporary prostatic splints (53855, C9769)

- Plasma Kinetic Vaporization (e.g., PlasmaKinetic™ Tissue Management System)
- Prostatic arterial embolization (PAE)
- Transrectal thermal therapy
- Transurethral ultrasound-guided laser incision of the prostate (TULIP)
- Water-induced thermotherapy (WIT) (also known as hot-water balloon thermoablation and thermourethral hot-water therapy)

Policy Guidelines

American Urological Association (AUA) symptom index (SI)
A questionnaire is often used to evaluate the severity of the condition. Several scoring systems have been developed to assess the subjective symptoms of BPH, including the American Urological Association (AUA) symptom index (SI). The AUA-SI test contains seven questions, and the resulting symptom score is from mild to severe. Each question is answered with a score ranging from 0 for none to 5 for severe. The symptom score (i.e., sum of the answers) is ranked as follows:

- Mild prostatism (0 to 7)
- Moderate prostatism (8 to 19)
- Severe prostatism (20 to 35)

The International Prostate Symptom Score (IPSS)
The International Prostate Symptom Score (IPSS) can be utilized to measure the severity of lower urinary tract symptoms. It is a validated, reproducible scoring system to assess disease severity and response to therapy. The IPSS is made up of 7 questions related to voiding symptoms. A score of 0 to 7 indicates mild symptoms, 8 to 19 indicates moderate symptoms and 20 to 35 indicates severe symptoms. It is not a reliable diagnostic tool for lower urinary tract symptoms (LUTS) suggestive of BPH but can be used to quantitatively measure LUTS after a diagnosis is made.

Calculator: International Prostatism Symptom Score (IPSS)

Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?

- ○ Not at all (0 points)
- ○ Less than 1 time in 5 (1 point)
- ○ Less than half the time (2 points)
- ○ About half the time (3 points)
- ○ More than half the time (4 points)
- ○ Almost always (5 points)

Over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?

- ○ Not at all (0 points)
- ○ Less than 1 time in 5 (1 point)

- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you found you stopped and started again several times when you urinated?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you found it difficult to postpone urination?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had a weak urinary stream?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how often have you had to push or strain to begin urination?

- Not at all (0 points)
- Less than 1 time in 5 (1 point)
- Less than half the time (2 points)
- About half the time (3 points)
- More than half the time (4 points)
- Almost always (5 points)

Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

- None (0 points)

- ○ 1 time (1 point)
- ○ 2 times (2 points)
- ○ 3 times (3 points)
- ○ 4 times (4 points)
- ○ 5 or more times (5 points)

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (when specified as prostate arterial embolization)
- 37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction (when specified as prostate arterial embolization)
- 52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant (used for the first implant) (Urolift)
- 52442 each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure) (Urolift)
- 52450 Transurethral incision of prostate
- 52647 Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)
- 52648 Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
- 52649 Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
- 53850 Transurethral destruction of prostate tissue; by microwave thermotherapy
- 53852 Transurethral destructions of prostate tissue; by radiofrequency thermotherapy
- 53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (Rezum)

- 53855 Insertion of a temporary prostatic urethral stent, including urethral measurement
- 55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
- 55880 Ablation of malignant prostate tissue, transrectal, with high-intensity focused ultrasound (HIFU), including ultrasound guidance
- 53899 Unlisted procedure, urinary system
- 55899 Unlisted procedure, male genital system
- C2596 Probe, image-guided, robotic, waterjet ablation
- C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants (Urolift)
- C9740 Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants (Urolift)
- C9769 Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts
- 0421T Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed) (Aquablation/transurethral waterjet ablation [e.g., AquaBeam System])
- 0619T Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed (Optilume)

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POLICY HISTORY

Date	Reason	Action
September 2022	Interim Review	Policy Revised
February 2022	Annual Review	Policy Revised
February 2021	Annual Review	Policy Revised
July 2020	Interim Review	Policy Revised
February 2020	Annual Review	Policy Revised
February 2019	Annual Review	Policy Revised

February 2018	Annual Review	Policy Revised
September 2017	Interim Review	Policy Revised
June 2017	Annual Review	Policy Revised
June 2016	Annual Review	Policy Revised
July 2015		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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