MEDICAL POLICY

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Medical Policy Title	**Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)**
Policy Number	**7.01.104**
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Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Minimally invasive treatment for benign prostatic hyperplasia (BPH) is **medically appropriate** when **ALL** of the following criteria are met:

A. Symptomatic benign prostatic hyperplasia (BPH);

B. As an alternative to Transurethral Resection of the Prostate (TURP) when **EITHER** of the following are met:

1. Non-surgical methods have been tried (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) for at least three (3) months; **or**
2. The patient is unable to tolerate non-surgical treatments;

C. With **ANY** of the following minimally invasive BPH treatments when associated criteria are met:

1. Prostatic Urethral Lift (PUL) (i.e., UroLift)
   a. Prostate volume 30-80cc;
   b. Absence of **ANY** of the following contraindications;
      i. Obstructive median lobe verified by cystoscopy;
      ii. Urethral conditions that may prevent insertion of delivery system into the bladder;
      iii. Signs and symptoms of a urinary tract infection;
      iv. Urinary incontinence due to incompetent sphincter; **or**
      v. Current gross hematuria;
2. Transurethral Water Vapor Thermal Therapy II (i.e., Rezūm)
   a. 50 years of age or older; **and**
   b. Prostate volume between 30-80cc;

3. Waterjet Ablation Therapy (i.e., Aquablation, Aquabeam)
    a. 45-80 years old; **and**
    b. Prostate volume 30-150cc; **or**
4. Prostate Artery Embolization (PAE) utilizing particle embolics
    a. Performed by an interventional radiologist trained in this procedure; and
    b. For **ANY** of the following clinical situations:
        i. Prostate volume 50cc or greater;
        ii. surgery is contraindicated (i.e. anesthesia risk, comorbidities, etc.); **or**
        iii. Gross hematuria from the prostate (regardless of size).

II. The following BPH treatments are considered **investigational**, including but not limited to:
    A. Transperineal Laser Ablation (TPLA);
    B. Temporary Implantable Nitinol Device (iTIND);
    C. Drug coated balloons (e.g. Optilume).

RELATED POLICIES

Corporate Medical Policy

7.01.01 Focal Therapies for Prostate Cancer

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The number of prostatic urethral lift implants will vary due to the unique characteristics of the prostate and prostatic urethra, but clinical data support an average of four (4) to five (5) implants per procedure.

II. PUL devices do contain nickel, patients that have a known allergy to nickel should have a discussion with their provider before consenting to the procedure.

DESCRIPTION

Benign prostatic hyperplasia (BPH) is one of the most common afflictions in the aging man. It is a histologic diagnosis defined as the proliferation of smooth muscle and epithelial cells within the transition zone of the prostate gland. The enlarged gland has been proposed to contribute to the overall lower urinary tract symptoms (LUTS) complex through direct bladder outlet obstruction (BOO) from enlarged tissue and from increased smooth muscle tone and resistance within the enlarged gland. Voiding symptoms have often been attributed to the physical presence of BOO. BPH does not necessarily require treatment. The decision to treat is based on an assessment of the impact of the symptoms on quality of life, which can be significant. Patients with persistent symptoms despite medical management may be considered for surgical treatment. The traditional standard treatment is

transurethral resection of the prostate (TURP).

Prostatic Urethral Lift (PUL) (e.g. UroLift System)

Prostatic urethral lift (PUL) system (e.g. UroLift System) is a minimally invasive, that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen and reducing urinary obstruction. The delivery device contains a preloaded implant that deploys a permanent tensioning suture. The suture runs from the urethra to the outer prostatic capsule and serves to pull the lateral lobe of the prostate away from the urethra. Implants are delivered bilaterally to separate the encroaching lobes. Four to five implants are typically inserted, but this varies with the size and shape of the prostate. The UroLift System may be used to treat prostate glands measuring less than 80 milliliters (mL) and is implanted by a urologist in an outpatient or inpatient setting. The transurethral procedure to insert UroLift is performed with the use of local or general anesthesia and oral sedation.

Transurethral Water Vapor Thermal Therapy (e.g. Rezūm System)

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. Transurethral water vapor thermal therapy is a transurethral needle ablation technique which injects radiofrequency-generated, sterile water vapor (~103 degrees C) into enlarged prostate tissue. As the steam encounters the prostatic tissue, it condenses back into water, releasing large amounts of thermal energy, disrupting the prostatic cell membranes, and leading to cell death and necrosis. It takes approximately three months for the body to reabsorb dead tissue, decreasing prostate volume and relieving LUTS. The thermal energy is confined to the prostrate, which reduces the risk of injury to other parts of the body. The procedure is performed under local anesthesia in an office or outpatient setting.

Transurethral Waterjet Ablation (e.g. Aquablation, Aquabeam)

Transurethral Waterjet Ablation (Aquablation) uses a specialized system that combines image guidance and robotics for the targeted heat-free removal of prostate tissue. The procedure is usually done with the patient under general or spinal anesthesia. Transrectal ultrasound is used throughout the procedure. A handpiece with an integrated cystoscope and ablation probe is inserted through the urethra and into the bladder. Positioning is confirmed by using visual markers on a computer screen, and the surgeon is able to plan the depth and angle of resection using the system software. Once the surgical mapping is complete, a high-speed jet of saline is delivered to the prostate at various flow rates, according to the depth of penetration needed. The ablated tissue is aspirated through ports in the handpiece and can be used for histological analysis.

Prostate Artery Embolization (PAE)

Prostate artery embolization (PAE) is a minimally invasive outpatient procedure that involves the release of microscopic, plastic beads into the arteries that feed the prostate gland. The beads travel to the patient's prosthetic arteries, and once there, they permanently block off the blood flow that is causing the swelling in the prostate.

Transperineal Laser Ablation (TPLA)

Transperineal Laser Ablation (TPLA) is a minimally invasive procedure that involves use of a diode

laser light which is passed through 300 µm optical fibers which are introduced transperineally and placed at a secure distance from urethra and bladder neck. EchoLaser Smart Interface assists easing needle positioning and increases safety. Several clinical trials are currently enrolling members for data collection.

Temporary Implantable Nitinol Device (iTIND)

Temporary implantable nitinol device (iTIND) is implanted cystoscopically and is designed to remodel the bladder neck and prostatic urethra through ischemic tissue necrosis and permanent mucosal incisions. iTIND was developed to be a truly minimally invasive, non-ablative therapy that does not carry the possible risks of leaving a permanent implant within the prostatic urethra. The iTind device expands and exerts pressure on prostatic tissue, causing ischemic necrosis, the creation of compression channels, and a remodeling of the prostatic urethra and the bladder neck. This stent-like device is left in place for only five to seven days before being removed.

Drug Coated Balloons (i.e., Optilume)

Transurethral balloon dilatation involves the insertion of a balloon catheter through the urethra into the prostatic urethra where it is inflated, theoretically pushing back prostate tissue and stretching the urethra where it has been narrowed by the prostate. An example of this includes but may not be limited to the Optilume Basic. The Optilume drug-coated balloon combines urethral dilation with circumferential topical delivery of paclitaxel.

SUPPORTIVE LITERATURE

Prostatic Urethral Lift

Roehrborn et al (2013) reported results of the L.I.F.T. (Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH) trial, which was the first multicenter, randomized, double-blinded trial of the prostatic urethral lift (PUL) for the treatment of LUTS secondary to BPH. Nineteen centers in three countries (United States, Canada, and Australia) enrolled 206 men, who were randomized 2:1 to treatment with either the PUL (n=140) or sham control (n=66) consisting of rigid cystoscopy. The primary endpoint was the reduction in AUASI at three months. Secondary measures included QOL, Benign Prostatic Hyperplasia Impact Index (BPHII), International Index of Erectile Function (IIEF), Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), Maximum urinary flow rate (Qmax), and PVR. Participants were followed for 12 months, with 123 PUL subjects included in the 12- month analysis. The primary endpoint was met with the PUL AUASI reduction 88% greater than sham control, 11.1 versus 5.9, respectively (p=0.003) and sustained at one year. Qmax increased 4.4 ml per second at three months and was sustained at 4.0 ml per second at 12 months, which was both clinically and statistically significant. Erectile function remained stable after the procedure. There were two serious adverse events, one clot retention and one bladder stone. Less serious adverse events (AE) (postoperative dysuria, hematuria, pain/discomfort, and urgency) were typically mild to moderate and resolved within two weeks. The authors concluded that the prostatic urethral lift provides a clinically meaningful improvement in LUTS secondary to BPH and urinary flow and can be performed under local anesthesia with low morbidity and preservation of sexual function.

Sønksen et al (2015) conducted a randomized trial known as the BPH6 study, comparing PUL to TURP to determine LUTS improvement, recovery, worsening of erectile and ejaculatory function, continence, and safety. A total of 80 men across 10 European centers received either PUL (n=45) or TURP (n=35). One patient in the PUL group was excluded from analysis for violation of the active urinary retention exclusion criteria. At 12-month follow-up, the PUL group demonstrated an average decrease of 11.4 in IPSS, while IPSS improvement after TURP was 15.4. PUL patients consistently had more rapid recovery than TURP patients (82% vs. 53% respectively). Significant improvements in IPSS, IPSS QoL, BPH II, and Qmax were observed in both groups over time. Erectile function was preserved in both PUL and TURP groups as measured by SHIM scores. The PUL group experienced an improvement in average ejaculatory score (MSHQEjD) from baseline ($p = 0.03$), but the TURP group suffered from a significant decline. For the BPH6 ejaculatory assessment, the response for the PUL group was 100%, significantly better than the 60.6% response for the TURP group ($p < 0.0001$). Continence preservation was comparable between the groups. The number of patients who experienced grade 2 and 3 adverse events was similar between groups. Of the participants who met the original BPH6 primary endpoint, 34.9% were in the PUL group and 8.6% were in the TURP group. Of the participants who met the modified BPH6 primary endpoint, 52.3% were in the PUL group and 20.0% were in the TURP group. Reintervention for failure to cure occurred in 6.8% (3/44) of PUL patients and 5.7% (2/35) of TURP patients (not significant). The authors concluded that both the PUL and TURP groups achieved significant symptom relief compared to baseline, with a superior symptom relief rate for TURP and a superior quality of recovery and preservation of ejaculatory function for PUL. Limitations include the short-medium follow-up, small sample size, and lack of blinding.

Roehrborn et al (2017) reported five-year results of the L.I.F.T. study. At five years of follow-up, data were available for 104 of 140 PUL subjects (74.3%). A total of 18 were lost to follow-up, nine died of unrelated causes; nine exited the study for other reasons. Surgical retreatment for failure to cure was 13.6%, with 4.3% receiving additional PUL implants and 9.3% undergoing TURP or laser ablation. The authors reported on two analyses, a per-protocol (PP) analysis and an intention-to-treat (ITT) analysis. A total of 72 patients were included in the PP analysis, after exclusions for protocol violations, additional BPH procedures, or treatment with BPH medication. Sustained improvements were reported based on the PP analysis in symptoms (36% IPSS), quality of life (50% QOL, 52% BPHII) and urinary flow rate (44% Qmax). No differences were seen between ITT and PP populations.

Gratzke et al (2017) reported two-year follow-up results from the BPH6 study. Over the two-year follow-up, six patients (13.6%) in the PUL group and two (5.7%) in the TURP group underwent secondary treatment for LUTS. Three additional patients discontinued study participation, resulting in 37 PUL patients and 32 TURP patients included in the two-year analysis. Significant improvements in International Prostate Symptom Score (IPSS), IPSS quality of life (QoL), BPH Impact Index (BPHII), and maximum urinary flow rate (Qmax) were observed in both groups throughout the two-year follow-up. Changes in IPSS and Qmax in the TURP group were superior to the PUL group. Improvements in IPSS QoL and BPHII score were not statistically different between the study groups. PUL resulted in superior quality of recovery, ejaculatory function preservation, and performance on the composite BPH6 index. Ejaculatory function bother scores did not change significantly in either

treatment group. TURP significantly compromised continence function at two weeks and three months. Only PUL resulted in statistically significant improvement in sleep.

Rukstalis et al (2019) reported on the MedLift study, an U.S. Food and Drug Administration (FDA) IDE extension of the L.I.F.T. randomized study designed to examine safety and efficacy of PUL for treatment of obstructive middle lobes (OML). Compared to lateral lobe subjects from the historical L.I.F.T. study, the 45 enrolled OML subjects' symptoms improved at least as much at every time point (OML range 13.5–15.9, LL range 9.9–11.1, p=0.01). The observed rate of post-procedure, device-related, serious complications was 0%, thereby achieving the primary safety composite endpoint. Published evidence, which includes the BPH6, L.I.F.T., and MedLift studies, support a clinically meaningful improvement in net health outcome.

Transurethral Water Vapor Thermal Therapy

McVary et al (2016) reported the results of a multi-center, randomized, controlled study (Rezum II study) using transurethral prostate convective water vapor thermal energy to treat LUTS associated with BPH. A total of 197 men aged 50 years and older were randomized 2:1 to thermal therapy, n=136, and control (insertion of a rigid cystoscope), n=61. The primary endpoint was an IPSS reduction at three months greater than 125% in the treatment group as compared to the control. Results showed IPSS was reduced by 50% compared with 20% reduction for control. Therapy outcomes for the treatment group, including Qmax, QoL ($p < 0.0001$) and BPHII ($p= 0.0003$), were significantly improved compared to control and sustained throughout 12 months. Two treatment subjects had three serious AEs adjudicated as procedure-related: extended urinary retention, nausea, and vomiting. The authors concluded that convective water vapor energy ablation of prostate adenomas provides statistically significant and clinically meaningful improvements within two weeks after treatment for LUTS due to BPH. Limitations of the study include the short follow-up period and small sample size.

McVary et al (2019) reported four-year outcomes of the randomized controlled trial of water vapor thermal therapy study. Out of the original 135 subjects who underwent water vapor therapy, 90 (66.7%) were included in the 48-month per protocol analysis. IPSS improvements from baseline remained consistent from the early response at three months (49.9%) to year 1 (52.2%), year 2 (50.7%), year 3 (49.7%), and year 4 (46.7%). Flowrate improvements were sustained relative to baseline, remaining significant, although an increase of 5.5 at one year to a mean 4.2 mL/s at four years was noted. Men with moderate and severe LUTS had symptomatic relief with similar IPSS improvements at four years of 46.1% and 46.9% and Qmax of 45% and 51.3%, respectively. QOL and BPH Impact Index remained improved at 43% and 52% respectively, $P <.0001$. Throughout the four years, urinary incontinence scores decreased significantly. Sexual function throughout two years after treatment shows that erectile function (IIEF) and ejaculatory function (MSHQ-EjD) scores remained unchanged but worsened at four years. At four years, surgical intervention was performed in six of 135 subjects (4.4%) including four subjects in whom a median lobe was identified but not treated. Comparatively, surgical retreatment rates for TUNA are 19.1% at three years and 14%-51% at five years. TUMT retreatment at five years is 8.9%-21%, and prostatic urethral lift procedure has a reported surgical retreatment of 10.6% at three years and 13.6% at five years. The authors concluded that water vapor thermal therapy provides effective symptom relief and improved QOL

that remained durable throughout four years.

McVary et al (2021) reported his final five-year outcomes of the randomized controlled trial for water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hypertrophy (BPH). Significant improvement of lower urinary tract symptoms was observed at <3 months post-thermal therapy, remaining durable through 5 years in the treatment group. At five years, the International Prostate Symptom Score reduced 48%, quality of life increased 45%, maximum flow rate improved 44%, and the Benign Prostatic Hyperplasia Impact Index decreased 48%. Surgical re-treatment rate was 4.4% with no reports of device or procedure related sexual dysfunction or sustained de novo erectile dysfunction.

In addition, the efficacy and safety of Rezum water vapor thermal therapy was further supported through a prospective pilot study, a crossover study, and two retrospective studies where outcomes demonstrated improvements in patients International Prostate Symptom Score (IPSS), quality of life (QoL), Qmax and post void residual (PVR) without causing deterioration of sexual function.

Evidence for transurethral water vapor thermal therapy mostly consists of one small, short-term, sham controlled RCT with a five-year uncontrolled follow-up phase. LUTS improved more in the intervention group (50%) compared to sham (20%) at three months. Improvements were sustained through four years of follow-up. No adverse events of erectile or ejaculatory function were observed with scores unchanged through two years of follow-up. Based on the single, short-term, sham-controlled study with a five-year uncontrolled follow-up phase, BPH treatment with water vapor thermal therapy resulted in improved health outcomes which remained stable throughout the five years.

Transurethral Waterjet Ablation (Aquablation)

Aquablation for treatment of BPH has been assessed in a single RCT, known as WATER (Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue). WATER was a noninferiority trial comparing aquablation with TURP in 181 participants at 17 sites in 4 countries. Participants were men ages 45 to 80 years with moderate-to-severe LUTS, defined as an IPSS 10 score ≥12, and prostate size between 30 and 80 cc. The primary efficacy endpoint was the difference between groups in the change in IPSS at 6 months, and the primary safety endpoint was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. Primary endpoint results were reported by Gilling et al in 2018, 12-month results in Gilling et al (2019), and 3-year results in Gilling et al (2020). Additionally, a synthesis of the trial results up to 12 months was reported in a Cochrane systematic review conducted by Hwang et al (2019). On the primary efficacy outcome, aquablation was noninferior to TURP. At 6 months, mean IPSS decreased from baseline by 16.9 points for aquablation and 15.1points for TURP (mean difference 1.8 points; p<.0001 for noninferiority and p=.1347 for superiority). The primary safety endpoint rate was lower in the aquablation group compared to the TURP group (26% versus 42%, p=.0149). The rate of grade two (2) and greater events was similar in the two groups (20% for aquablation and 23%for TURP; p=.3038).

Berjaoui et al (2024) conducted a study to compare the long-term outcomes of Aquablation for small-to-moderate prostates (30-80 mL) in the WATER clinical trial, with the outcomes for large prostates

(80-150 mL) in the WATER II clinical trial at a 5-year follow-up. Participants that made it to the 5-year follow up were 60 subjects from WATER II and 58 participants from WATER, just under half did not make it to the 5-year mark. Patients completed IPSS and Incontinence Severity Index (ISI) questionnaires. Also measured was uroflowmetry, PVR measurements, and standard laboratory testing. These questionnaires were repeated at months 1, 3, 6, 12, 24, 36, 48, and 60 months. PSA was repeated and 6 months and annually thereafter. Results demonstrated improvement in from baseline to 60 months in IPSS: WATER (22.9 to 7.0) and WATER II (23.2 to 6.8), Qmax: WATER (9.4 to 17.3 cc/s) and WATER II (8.7 to 17.1 cc/s). At the 5-year follow-up, patients that were medication-free for BPH (WATER: 99% and WATER II: 94%) and free from surgical retreatment (WATER: 95%; WATER II: 97%).

Prostate Artery Embolization (PAE)

Sapoval et al (2023) conducted the PARTEM trial which compared prostatic artery embolization versus medical treatment in patients with benign prostatic hyperplasia. A randomized, open-label, superiority trial was set in 10 French hospitals. Patients with bothersome LUTS defined by International Prostatic Symptom Score (IPSS) > 11 and quality of life (QoL) > 3, and BPH ≥50 ml resistant to alpha-blocker monotherapy were randomly assigned (1:1) to PAE or Combined Therapy ([CT], oral dutasteride 0.5 mg/tamsulosin hydrochloride 0.4 mg per day). The primary outcome was the 9-month IPSS change. Ninety patients were randomized from September 2016 to February 2020, and 44 and 43 patients assessed for primary endpoint in PAE and CT groups, respectively. The 9-month change of IPSS was −10.0 (95% confidence interval [CI]: −11.8 to −8.3) and −5.7 (95% CI: −7.5 to −3.8) in the PAE and CT groups, respectively. This reduction was significantly greater in the PAE group than in the CT group (−4.4 [95% CI: −6.9 to −1.9], p = 0.0008). The IIEF-15 score change was 8.2 (95% CI: 2.9–13.5) and −2.8 (95% CI: −8.4 to 2.8) in the PAE and CT groups, respectively. No treatment-related AE or hospitalization was noticed. After 9 months, 5 and 18 patients had invasive prostate retreatment in the PAE and CT group, respectively. The authors concluded that this study showed in patients with BPH ≥50 ml and bothersome LUTS resistant to alpha-blocker monotherapy, PAE provides more urinary and sexual symptoms benefit than CT up to 24 months. This trial demonstrates that, at 9 months and up to 24 months, PAE provides better urinary and sexual symptoms score benefit than combined therapy in patients with bothersome LUTS related to BPH ≥50 ml not responsive to a one-month trial of alpha blockers.

Bhatia et al (2025) conducted a retrospective study evaluated the mid- to long-term safety and effectiveness of prostatic artery embolization (PAE) in 1,075 patients treated at a single center between January 2014 and July 2023. Patients had moderate-to-severe lower urinary tract symptoms (LUTS) or urinary retention who had undergone PAE. They were followed for a mean of 458.4 days and assessed at 1, 3, 6, and 12 months after PAE and thereafter. Mean prostate volume (PV) was 107 grams, and the median preprocedural IPSS was 23, QoL was 5, and IIEF-5 score was 17 and PSA level was 4.7ng/ml. In the LUTS subgroup, at 1–3, 6–12, and 48–60 months, the median IPSS values were 7, 6, and 9, respectively. Of 126 patients in the retention cohort, 119 (94%) were catheter-free at the 3-month follow-up. Up to 60 months after PAE, 90 patients (16% of reintervention eligible patients) required a second prostatic intervention. After PAE, 65.5% of patients were BPO medication–free at 1 year. Adverse events were rare in 7 patients and resolved without lasting effects, including prostate sloughing, urosepsis and transient ischemic attacks. Overall, PAE

demonstrated durable symptom relief, improved quality of life, and a favorable safety profile with sustained relief up to 60 months.

Brown et al (2024) conducted a randomized controlled trial to assess PAE as a first line therapy compared to medication in treatment of naïve men with prostate enlargement known as the P-EASY ADVANCE trial. The trial consisted of at 39 men with enlarged prostates, moderate-severe lower urinary tract symptoms and obstructed/equivocal urodynamic studies (UDS), and who had no prior treatment for BPH. They were randomized to receive either combined medical therapy or PAE. Follow-up was conducted by assessing UDS, International Prostate Symptom Score (IPSS), uroflowmetry and ultrasound at short- to medium-term intervals and compared to baseline. Both interventions improved voiding and bladder outflow obstruction from baseline (unobstructed after PAE 63%, medication 28%). PAE patients had greater reduction in prostate size, incomplete emptying, total IPSS, and quality of life. In the medication group, altered ejaculation, erectile dysfunction and nausea were more common. Although PAE showed to be more effective than the combined medical therapy, authors state that "further randomized comparative trials are planned to validate the role of PAE in mitigating obstructive BPH."

Müllhaupt et al (2024) conducted a randomized, open-label, single center trial of 103 patients with refractory LUTS/benign prostatic obstruction (BPO). They aimed to compare the safety and efficacy of PAE and TURP treatment at 5-year follow up. Primary outcome was the change in IPSS after PAE versus TURP. Secondary outcomes included patient-reported outcomes, functional measures and adverse events. The outcomes were measured at 3, 6, 12, 24, and 60 months. Of the randomized patients with LUTS/BPO, 18/48 in the PAE group and 38/51 in the TURP group completed 5-year follow-up. Mean IPSS reduction was -7.78 for PAE and -11.57 for TURP (difference 3.79; 95% CI -0.66 to 8.24). TURP showed superior patient-reported outcomes except erectile function. At 5 years, TURP was more effective than PAE in improving urinary flow (9.30 vs 3.59 ml/s; difference -5.71) and reducing postvoid residual volume (219.97 vs 27.81 ml; difference 192.15). The study had notable limitations. Blinding of patients and physicians wasn't possible, and five patients per group were lost to follow-up. Additional dropouts left only 18 PAE and 38 TURP patients for analysis, reducing statistical power and preventing subgroup analysis. This likely contributed to the loss of significance in some comparisons at the 5-year follow-up. Furthermore, five of 20 patients who required TURP after unsatisfactory PAE outcomes could only undergo unilateral embolization, which may have impacted results. The authors state "the improvements in subjective and objective outcomes are more pronounced after TURP and thus PAE is not a definitive treatment in the long term for a relevant proportion of patients, especially those with advanced LUTS/BPO stage requiring maximum relief of bladder outlet obstruction."

Marchi et al (2023) conducted a retrospective single-center with the primary objective to assess long-term outcomes of PAE in 88 patients with acute urinary retention related to BPH. Urinary catheter was attempted at two weeks post PAE, success was defined as the absence of acute urinary retention recurrence. In the month following catheter removal 82% of patients were successful and 16% had immediate recurrence. Clinical success persisted for 66% of patients at long term follow-up (mean follow-up: 19.5 months ±16.5 [SD]; range: 2–74 months). Recurrence occurred at a mean of 16.2 months ±12.2 (SD) (range: 1.5–43 months) post-PAE. Overall, 24% patients of the cohort underwent prostatic surgery, at a mean of 10.4 months ± 12.2 (SD) (range: 1.2–42.4 months) from

initial PAE. No correlations between patient variables or bilateral PAE and long-term clinical success were identified. Kaplan-Meier analysis showed a three-year catheter free probability of 60%. They state that further investigation is needed in patients with acute urinary retention (AUR) recurrence during long-term follow-up.

Carnevale et al (2020) conducted a retrospective single center study in 317 patients with moderate to severe BPH. Participants were followed for 96 months to evaluate the efficacy and long-term results of PAE for BPH. Participants received PAE, 94% received bilateral and 6% received unilateral. Over a median follow-up of 72 months, early clinical failure occurred in 1.9%, and 23% experienced symptom recurrence significantly higher in the unilateral group (42% vs. 21%). Average improvements included a 16-point drop in IPSS, 4-point improvement in quality-of-life score, 39 cm^3 reduction in prostate volume (39%), a 6 mL/sec increase in urinary flow (155%), and a 70 mL decrease in postvoid residual volume (48%), all statistically significant ($P < .05$). Higher baseline PSA levels were linked to lower recurrence risk (HR 0.9; 95% CI: 0.8–0.9; $P < .001$). Embolization with mixed particle sizes (100–500 µm group vs 300-500 µm group) showed no significant impact on recurrence. No patients reported urinary incontinence or erectile dysfunction. Limitations included, that early PAE procedures lacked cone-beam CT, cone-beam CT has since enhanced pelvic anatomy visualization and reduced both procedure and radiation time. Baseline IPSS was missing for men with catheters. Over 10 years, varied techniques and embolic agents were used, limiting consistency. Few patients had over five years of follow-up. The authors state that "although long-term results for PAE are promising, further investigations regarding optimal technical aspects of the procedure and patient selection are still required" stating that the data indicates it is a safe and effective procedure and has the potential to become an alternative procedure for BPH.

Transperineal Laser Ablation (TPLA)

Bianco et al (2021) presented at the 2021 American Urological Association annual meeting, the six month and twelve-month results of a study called transperineal laser ablation for benign prostatic hyperplasia (BPH): Feasibility and safety. This study was a Phase I trial, trial, whose objective was to evaluate feasibility and safety as well as three-, six- and twelve-months outcomes for TPLA. Twenty subjects were enrolled in this study. All subjects had complete lower urinary tract evaluation with pressure flow studies, international prostate symptom scores (IPSS) and sexual health inventory for men (SHIM) scores and ultrasonographic prostate volume measurements. Renal function biomarkers as well as PSA were collected. The protocol called for 2-4 Echolaser4 (Elesta Els, Italy) TPLA applications in the prostate under ultrasound guidance aided by the ELS tracing system. Although functional outcomes are pending, a 4-point median improvement in IPSS scores was seen at thirty days.

Temporary Implantable Nitinol Device (iTIND)

Kadner et al (2020) reported on the results of a single-arm, multicenter, international, prospective study that was conducted at nine sites from December 2014 to December 2016 under clinical trial NCT02145208. 81 men with symptomatic BPH (IPSS≥10, peak urinary flow <12mls/s and prostate volume < 75mls) were enrolled in this study. Kadner, et al., notes that a wash-out period of one month for alpha-blockers and six months for 5-alpha reductase inhibitors (5-ARIs) was mandatory to avoid variable confusion. The procedure was performed under light sedation with

device implanted and removed five to seven days later with topical sedation. A total of 51 men completed follow up after two years. Mean Qmax and PVR were 7.62 ± 2.25 ml/s and 65.84 ± 38.46 ml at baseline, and IPSS and QoL scores were 20.51 ± 4.58 and 3.96 ± 0.87, respectively. Implantation procedures elicited average pain VAS scores of 3.2 ± 1.6 and were all technically successful with no intraoperative complications. Implants were retrieved 5.7 ± 0.9 days after deployment. All objective and subjective measures showed statistically significant improvements ($p < 0.0001$) from baseline levels at all assessment points. IPSS urinary symptoms were reduced by 12.00 ± 6.12 points at the end of the follow-up period. Quality of life scores reflected symptomatic relief, with patients reporting a mean reduction of 2.4 points from baseline. Maximum urinary flow rate (Qmax) rose to 16.00 ± 7.43 ml/s, an average increase of 8.38 ± 7.93 ml/s. No deterioration in PVR was observed by the end of the follow-up period. Results suggest that iTind implantation for treatment of LUTS secondary to BPH is associated with minimal perioperative morbidity and provides rapid symptomatic and functional outcomes that are durable through 24 months follow-up. The need for reoperation or de-novo-medication is very low, except in patients with median lobes, who so far cannot be recommended for treatment. In contrast to medical and surgical alternatives, there is an indication that treatment with iTind does not pose a risk to ejaculatory and sexual functions, but this finding must be supported with further studies. The European Association of Urology guidelines acknowledge the emerging role of this device, no specific recommendation is given, and its formal role is therefore yet to be defined.

Drug Coated Balloon (i.e., Optilume)

Kaplan et al (2024) reported the 2-year long-term follow up from the PINNACLE study, a prospective, multicenter, randomized study that was evaluating the safety and effectiveness of the Optilume BPH catheter system. The study consisted of 148 men with symptomatic BPH, who were randomized in a 2:1 fashion to Optilume or a Sham. Success was measured by IPSS, peak urinary flow rate (Qmax), post void residual (PVR) urine, quality of life and sexual function, follow-up beyond 1 year was limited to those treated with the Optilume product. At 2 years 67.5% of participants treated with Optilume were considered symptomatic responders. Symptomatic responders are defined by ≥30% improvement in IPSS without medical or surgical retreatment. IPSS improved from 23.4 to 11.0, Qmax improved by 116.8% to 19%, PVR had a reduction (83.7 ± 70.3 (n = 99) to 65.9 ± 74.5 (n = 65)).

Kaplan et al (2024) reported the 4-year results of the prospective single arm, open-label, multicenter EVEREST clinical study. The study aimed to gather initial safety and efficacy data of the Optilume BPH Catheter System for the treatment of lower urinary tract symptoms (LUTS) secondary to BPH. The study consisted of 80 men with moderate-to-severe LUTS secondary to BPH who were treated with Optilume. Symptoms were assessed using IPSS, BPH Impact Index, Qmax and PVR. Previously reported symptom improvements were maintained through 4-year follow-up, which included reduction in IPSS and IPSS quality of life. Qmax was maintained in majority of men, with an average improvement from baseline and no adverse events were reported. Some limitations of the study include the lack of a control group and small number of participants.

PROFESSIONAL GUIDELINE(S)

The American Urological Association (AUA) published guidelines for the management of lower urinary tract symptoms attributed to BPH (Goueli 2026). They recommend the following:

- "Clinicians should offer procedural therapies for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (rUTIs), recurrent bladder stones or gross hematuria due to BPH, and/or LUTS/BPH refractory to other therapies, or are unwilling to use other therapies. (Clinical Principle).
- Clinicians should offer photoselective vaporization of the prostate (PVP) as an option for patients for the treatment of LUTS/BPH. (Strong Recommendation; Evidence Level: Grade B).
- Clinicians should offer PUL as an option for patients with prostates 30-80 cc without an obstructing median lobe for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).
- Clinicians should offer Water Vapor Thermal Therapy (WVTT) as an option for patients with prostates 30-80 cc for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).
- Clinicians should offer Robotic Waterjet Treatment (RWT) as an option for patients with prostates 30-80 cc for the treatment of LUTS/BPH. (Moderate Recommendation: Evidence Level: Grade B).
- Clinicians may offer RWT as an option for patients with prostates 80-150 cc for the treatment of LUTS/BPH. (Expert Opinion).
- Clinicians may offer Intraprostatic Drug Coated Balloon (IPDCB) as an option for patients with prostates 20-80 cc, a prostatic urethral length 32-55 mm, and without an obstructing median lobe for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade C).
- Clinicians may offer PAE with particle embolics as an option for patients with prostates ≥50 cc for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B).
- Urologists should assess patients with LUTS/BPH who are considering PAE prior to the procedure. (Expert Opinion).
- PAE should be performed in patients with LUTS/BPH by interventional radiologists specifically trained in PAE. (Expert Opinion).
- Clinicians should counsel patients with LUTS/BPH that PAE exposes them to radiation. (Clinical Principle).
- Clinicians should not offer high-intensity focused ultrasound (HIFU) ablation/cavitation or cryoablation to patients for the treatment of LUTS/BPH outside the context of a clinical trial. (Expert Opinion)."

<u>Prostatic Urethral Lift (PUL) (i.e., UroLift)</u>

The National Institute for Health and Care Excellence (NICE) 2021 guidelines for UroLift for treating LUTS of BPH states evidence supports UroLIft System for treatment as this can relieve LUTS, avoids risk to sexual function, and improves quality of life. NICE recommends UroLift as an alternative to

TURP and holmium laser enucleation of the prostate (HoLEP) for people 50 years or older with prostate volume 30-80ml.

NICE (2014) guidelines for insertion of prostatic urethral lift implants to treat LUTS secondary to BPH state evidence is adequate to support use of this procedure with the understanding that it's not likely to offer permanent relief of symptoms. Subsequent treatments are possible after this procedure though PUL may help prolong drug therapy and preserve sexual function compared to other interventions.

Transurethral Water Vapor Thermal Therapy II (i.e., Rezūm)

NICE (2020) guidelines for Rezum for treating LUTS secondary to BPH state that Rezum relieves LUTS and improves quality of life. They recommend this technology be considered for people with moderate to severe LUTS (International Prostate Symptoms Score [IPSS] typically 13 or over) and prostate size 30-80cm3.

Waterjet Ablation Therapy (Aquabeam)

NICE (2023) guidelines for transurethral water jet ablation for lower urinary tract symptoms caused by BPH states that there is good quality evidence that the procedure improves lower urinary tract symptoms caused by BPH and is safe enough to use with standard arrangements and raises no major safety concerns.

Prostate Artery Embolization (PAE)

NICE (2018) prostate artery embolization for LUTS caused by BPH guidelines state that current evidence supports the use of PAE. Patient selection should be done by a urologist and interventional radiologist with PAE being performed by an interventional radiologist with specific training and expertise in PAE.

The Society of Interventional Radiology (SIR) published practice guidance for PAE (Mouli 2026). They provide the following recommendations:

- PAE is recommended as a minimally invasive treatment option for appropriately selected men with BPH and moderate to severe LUTS.
- PAE can be appropriate for patients with prostates ≥50 mL. Prostates 30–49 mL may be considered on a case-by-case basis, although the evidence base for PAE is strongest for prostates ≥50 mL.
- Patients should undergo urologic evaluation for LUTS attributed to BPH, including assessment of medical history, physical examination, subjective symptom assessment (e.g., IPSS), urinalysis, and renal function.
- PAE should be performed by interventional radiologists with specialized training in the procedure and experience in embolization techniques. This includes proficiency in mesenteric or pelvic angiography, experience in microcatheterization, and experience in super selective embolization.

Temporary Implantable Nitinol Device (iTIND)

NICE 2022 technology briefing for iTind for lower urinary tract symptoms caused by BPH states evidence suggests that iTind improves symptoms and quality of life and is associated with expected, short-term, mild, transient and self-resolving complications. Although further research is needed, including a large multicenter RCT and showing comparative long-term patient outcomes. NICE panel experts agreed iTind is unlikely to replace standard care.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates BPH treatment systems as medical devices. All BPH treatment systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Oct 15]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls and Early Alerts | FDA [accessed 2026 Oct 15]

Transurethral Water Vapor Thermal Therapy II (i.e., Rezūm)

The Rezūm System (NxThera, Inc., Maple Grove, MN) received Section 510(k) approval from the FDA in August 2015.

The FDA indications for Rezūm System are:

- Men ≥ 50 years of age;
- Prostate volume ≥ 30 cm^3 and ≤ 80 cm^3;
- Intended to relieve symptoms, obstructions;
- Reduce prostate tissue associated with BPH;
- Treatment of prostate with hyperplasia of the central zone and/or median lobe.

Prostatic Urethral Lift (PUL) (i.e., UroLift)

In 2013, the FDA granted a de novo classification clearance for the UroLift System.

In January 2017, the FDA granted Section 510(k) clearance for the UroLift System (UL400 and UL500) for the treatment of symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia, in men 45 years of age or older.

In December 2019, the FDA modified the list of contraindications for the UroLift System (UL400) from prostate volume greater than 80 cc to prostate volume greater than 100 cc. The FDA indicated that its decision was based on clinical review of both sponsored and independent clinical studies that included men with prostate volumes greater than 80 cc, which showed that the symptom response, quality of life, uroflowmetry, adverse events, and catheterization rates were equivalent to the outcomes of patients with prostate volumes less than 80cc.

In June 2020, the FDA granted section 510(k) clearance for the UroLift Advanced Tissue Control

(ATC) System. A modification of the UroLift UL400 System, where the primary difference is the addition of a wing component on the distal tip of the UL400 which provides a larger footprint. This design feature is intended to provide better mobilization of tissue when performing the UroLift System procedure.

In July 2020, the FDA granted Section 510(k) clearance for the UroLift 2 System (UL2) for the treatment of urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia in men 45 years of age and older. The UL2 system is substantially equivalent to previous cleared generation devices. Minor device modifications have been made to the UL2 Delivery System (Delivery handle and implant cartridge) that do not affect the overall safety and effectiveness of the UroLift procedure. No modifications have been made to the UroLift Implant.

In 2020, the FDA expanded coverage of the UroLift system to treat prostates between 80-100 ccs.

The FDA Contraindications for the UroLift System are:

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

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0714T (E/I)	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL
0867T (E/I)	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (e.g., congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms) (e.g., PAE)

Code	Description
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction (e.g., PAE)
52284 (E/I)	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed (e.g., Optilume for urethral stricture)
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant (e.g., PUL)
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure) (e.g., PUL)
52443 (E/I)	Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a nondrug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed (e.g., Optilume for BPH)
52597	Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (e.g., Rezum)
53865 (E/I)	Cystourethroscopy with insertion of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate (e.g., iTIND)
53866 (E/I)	Catheterization with removal of temporary device for ischemic remodeling (i.e., pressure necrosis) of bladder neck and prostate (e.g., iTIND)

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HCPCS Codes

Code	Description
C2596	Probe, image guided, robotic, waterjet ablation
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants

ICD10 Codes

Code	Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Fluid Jet System Treatment for LUTS/BPH (L38367) [accessed 2026 Oct 15]

Fluid Jet System Treatment for LUTS/BPH (Billing and Coding A56797) [accessed 2026 Oct 15]

Therapeutic Embolization (NCD 20.28) [accessed 2026 Oct 15]

Prostatic urethral lift is not addressed in National or Regional Medicare coverage determinations or

policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
06/18/20, 06/17/21, 07/21/22, 09/21/23, 09/19/24, 05/22/25, 10/16/25, 11/19/26	
Date	**Summary of Changes**
11/19/26	• Annual review, policy statement for PAE updated to include prostate size 50cc or greater.
08/04/26	• Policy edit, Professional Guidelines section updated to reflect 2026 AUA update; PAE grade changed from C to B.
12/31/25	• Code edit, added 52597 to replace 0421T, added 52443 to replace 0619T. Policy intent unchanged.
11/03/25	• Policy edit for clarification of PS I.C.4
10/16/25	• Off-cycle review, prostate artery embolization (PAE) was updated from investigational to medically appropriate for specific indications.
05/22/25	• Off-cycle review, policy statement revised for aquablation to increase prostate size to 150 mLs and added drug coated balloon catheters (e.g. Optilume) to the list of investigational procedures. Code edits, added 52284 and C2596.
01/01/25	• Summary of changes tracking implemented.

06/18/20	• Original effective date